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FΡΔ	REGISTR	ΔΤΙΟΝ	NUMBER	2724-446 -	- VOI	4

#### Burnett, Gina

From:

Burnett, Gina

Sent:

Wednesday, March 21, 2018 1:06 PM

To:

Burnett, Gina

Subject:

RE: Urgent!-State Label Issue Tracking System for product # 002724-00446 (ZOECON RF-437 MOSQUITO GROWTH REGULATOR

SR-20)-Urgent!

Follow Up Flag: Flag Status: Follow up Flagged

LITS REPONSE POSTED 3/21/20318

The Biopesticides and Pollution Prevention Division (BPPD) has received your SLITS inquiry and your highlighted version of the EPA accepted master label for Zoecon RF-437 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446. BPPD has reviewed the label and determined the following:

- This label does not restrict aerial application only the sites specified in the highlighted paragraph: tires and tire piles, potted plants, tree holes, garbage bins, cans, birdbaths, rain barrels, and other water-holding containers and small bodies of water. Application may be made "by aircraft to terrestrial locations where mosquito breeding occurs" as long as the application rates on the label are followed. This includes all use sites on the label: freshwater swamps and marshes, salt marshes, woodland pools and meadows, dredging spoil sites, drainage areas, waste treatment and settling ponds, ditches and other natural and manmade depressions, as well as crop sites such as vineyards, rice fields, date palm orchards, fruit and nut orchards and berry fields and bogs. EPA acknowledges that the label should be revised to make this more clear.
  - O According to EPA's Fact Sheet on Insect Growth Regulators, this pesticide active ingredient is not harmful to birds or mammals, but can be somewhat toxic to some fish and aquatic invertebrates. Risk assessments show that the concentrations of active ingredient in aquatic environments, if the products are used according to label directions, should be well below the levels that are harmful in laboratory toxicity tests.
  - o This pesticide active ingredient is exempt from the requirement of a tolerance on all food commodities per 40 CFR 180.1033.
- Label revisions for this product will be required at the time of the applicant's next EPA label amendment submission.

Thank you for your question. Let us know if we can help you further.

Best Regards, Gina Burnett, BPPD/OPP/EPA

#### Gina Burnett

Senior Regulatory Advisor Biochemical Pesticides Branch (BPB) Biopesticides and Pollution Prevention Division (BPPD) Office of Pesticide Programs
U.S. Environmental Protection Agency
<u>burnett.gina@epa.gov</u>
(703) 605-0513 (phone)
(703) 305-0118 (fax)

From: US EPA Domino Webhosting Authority [mailto:domino.webmasters@epamail.epa.gov] On Behalf Of SLITS Administrators

Sent: Tuesday, March 20, 2018 10:10 PM

To: Bryceland, Andrew <Bryceland.Andrew@epa.gov>; Burnett, Gina <Burnett.Gina@epa.gov>

Cc: Hollis, Linda < Hollis.Linda@epa.gov>; Cathy.M.Tarutani-Weissman@hawaii.gov

Subject: Urgent!-State Label Issue Tracking System for product # 002724-00446 (ZOECON RF-437 MOSQUITO GROWTH REGULATOR SR-20)-Urgent!

A new request was created in the State Label Issue Tracking System on 3/20/2018 by Cathy Tarutani, in reference to product # 002724-00446 (ZOECON RF-437 MOSOUITO GROWTH REGULATOR SR-20).

Click here to view the request.

Please create your SLITS response to the requester by COB 3/22/2018

# PROCESSING REQUEST

Reg # 2724-446	eg # 2724-446 Decision # 518021		
Description: Pesticide Registration Improvement Act (PRIA) Labeling Amendment – Label amendment plus supplemental labeling to add aerial applications and update tank mixing directions			
Electronic Label & Letter (see PPLS):	Non Electronic OR Label & Letter (Scanning required):		
Dated: 09.29.16	☐ Dated:		
Other Materials Sent (se	ee jacket):		
and clipped together, NOT STAPLED. T materials to staff in the Information Se	rials in the jacket. It must be well organized then give the jacket with the coversheet and rvices Center (ISC) (Room S-4900). If a lige, please file materials in a new jacket and information please call 703-605-0716.		
Reviewer: Menyon Adams			
Division: BPPD	D		
Phone: 703-347-8496	Date: 09.29.16		

# PROCESSING REQUEST



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

September 29, 2016

Nancy Huebl Senior Registration Specialist Wellmark International 1501 East Woodfield Road, Suite 200W Schaumburg, Illinois 60173

Subject: Pesticide Registration Improvement Act (PRIA) Labeling Amendment - Label

amendment plus supplemental labeling to add aerial applications and update tank

mixing directions

Product Name: Zoecon RF-437 Mosquito Growth Regulator SR-20

EPA Registration Number: 2724-446 Application Date: May 26, 2016 OPP Decision Number: 518021

Dear Ms. Huebl:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

The supplemental labeling contains some new and/or revised uses and/or directions that may be additional to the uses and/or directions found on the labeling on or attached to the container, but the supplemental labeling does not by itself constitute the complete set of use directions. The complete set of use directions is set forth on the container labeling as combined with the supplemental labeling.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 § CFR 152.3.

Page 2 of 2 EPA Reg. No. 2724-446 OPP Decision No. 518021

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Menyon Adams of my branch by phone at (703) 347-8496 or via email at adams.menyon@epa.gov.

Sincerely,

Andrew Bryceland, Team Leader Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs

inview ! Eyeston -

Enclosure

#### [] optional wording

#### ZOECON RF-437 MOSQUITO GROWTH REGULATOR SR-20

Alternate brand names: Zoëcon® Altosid® Liquid Larvicide Concentrate

Strike® Midge Control

Prevents emergence of adult floodwater mosquitoes

[Prevents the emergence of adult filter [moth] flies, and midges]

[Keeps infestations under control]

Prevents emergence of adult fleas up to 8 weeks outdoors

Controls pre-adult fleas (larvae) up to 8 weeks

Biorational [approach to] flea control outdoors

Microencapsulated Formula

Prevents adult mosquito emergence (including those which may transmit West Nile Virus, Zika, chikungunya and dengue)

For control of mosquito larvae using ULV application

#### ACTIVE INGREDIENT:

(S)-Methoprene (CAS #65733-16-6)	20%
OTHER INGREDIENTS:	80%
TOTAL	100%

Formulation contains 1.72 lb/gal (205.2 g/l) active ingredient

## KEEP OUT OF REACH OF CHILDREN CAUTION

See Back Panel For Additional Precautionary Statements

BECAUSE OF THE UNIQUE MODE OF ACTION OF ZOËCON® RF-437 MOSQUITO GROWTH REGULATOR SR-20, SUCCESSFUL USE REQUIRES FAMILIARITY WITH SPECIAL TECHNIQUES FOR APPLICATION TIMING AND TREATMENT EVALUATION. SEE GUIDE TO PRODUCT APPLICATION OR CONSULT LOCAL MOSQUITO ABATEMENT AGENCY.

EPA Reg. No. 2724-446 EPA Est. No.

NET CONTENTS:

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ACCEPTED

09/29/2016

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2724-446

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#### PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

Call a poison co	ontrol center or doctor immediately for treatment advice.
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
If on skin or clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> </ul>
	ct container or label with you when calling a poison control center or doctor, or nent. You may also contact 1-800-248-7763 for emergency medical treatment

[Note: First Aid statement paragraph format may be used if space is limited.]

#### **ENVIRONMENTAL HAZARDS**

Do not contaminate water when disposing of rinsate or equipment washwaters.

#### **[INTRODUCTION]**

[Zoecon RF-437 is a unique product that controls [mosquitoes][filter [moth] flies (*Psychoda* spp.)][midges (*Chironomidae*)] and other nuisance aquatic insect species [infesting waste water treatment facilities]. Zoecon RF-437 contains an insect growth regulator (IGR) that is efffective on the developing [immature] stages of insect pests. Zoecon RF-437 does not kill adults but affects the larval stages as they grow and develop. Zoecon RF-437 stops the formation of pupa of insect pests, thereby eliminating adult populations. Zoecon RF-437 stops the cycle of reproduction, keeping pest infestations under control. Continued use of the product prevents these pests from rebounding into unmanageable infestations.]

#### DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

#### MIXING AND HANDLING INSTRUCTIONS:

- SHAKE WELL BEFORE USING. Zoecon RF-437 may separate on standing and must be thoroughly agitated prior to dilution.
- 2. Do not mix with oil; use clean equipment.
- 3. Partially fill spray tank [container] with water; then add the labeled amount of Zoecon RF-437, agitate and complete filling. Mild agitation during application is desirable. [Accomplish agitation by use of recirculation pump, mixer, air pump, or other suitable equipment.]
- Use spray solution within 48 hours; always agitate before spraying.

#### **APPLICATIONS**

**Mosquito Control:** Zoecon RF-437 must be applied to 2nd, 3rd, or 4th larval instars of target mosquitoes to prevent adult emergence. Treated larvae continue normal development to the pupal stage where they die. This insect growth regulator has no effect when applied to pupae or adult mosquitoes. Zoecon RF-437 has sufficient field life to be effective at label rates when applied to larval stages under varying field conditions. For further information, see **Guide to Product Application**.

#### For Control of Mosquito Larvae Using ULV Application:

For ground and aerial application to terrestrial sites, apply at the rate of ¾ - 1 fluid ounce of product per acre to water-holding containers and other small bodies of water that breed mosquitoes. Use equipment capable of applying a fine mist or ULV. Follow equipment manufacturer's recommendations when making applications. Direct spray applications to sites where mosquitoes breed. These sites include tires and tire piles, potted plants, tree holes, garbage bins, cans, birdbaths, rain barrels, and other water-holding containers and small bodies of water.

For aerial application to terrestrial sites, apply by fixed wing or rotary aircraft. Apply at the rate of 3/4 - 1 ounce of product to acre diluted with water at a minium of a 1:1 mix ratio with water. Apply using ULV equipped and capable aircraft. Unlike ULV sprays targeting flying mosquitoes, it is important that spray droplets deposit in targeted areas. Target terrestrial areas where mosquitoes breed. These sites include tires, open containers, garbage bins, birdbaths, and gutters holding small amounts of water. Spray equipment must be adjusted so that the volume median diameter (VMD) produced ranges from 60 microns (Dv<sub>0.5</sub> < 60µ) to 100 microns (Dv<sub>0.5</sub> < 100 $\mu$ ), and that 90% of the spray is contained in droplets smaller than 200 microns ( $Dv_{0.9}$  < 200µ). Directions from the equipment manufacturer or vendor, pesticide registrant, or test facility using a wind tunnel and laser-based measurement instrument must be used to adjust equipment to produce acceptable droplet size spectra. Application equipment must be calibrated annually to confirm that nozzle flow rate(s) are accurate. Do not apply at altitudes below 100 feet unless using unmanned aircraft designed for low application heights. Apply when wind speed on the ground is ≥ 1 mph and ≤ 10 mph. Apply when when wind factors promoting drift are low. For best results, use Global Positioning System (GPS) equipped aircraft.

[Waste Water Treatment Facility Pests: Use Zoecon RF-437 in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where midges, filter [moth] flies, and other nuisance aquatic insect pests are a problem.]

## [What to Expect in Waste Water Treatment Facilities] [Continuous Flow Sewage {waste water}

In order to achieve effective results, Zoecon RF-437 must be applied on a daily basis for at least 2 weeks. Failure to apply the material on a daily basis during the treatment phase may result in erratic results. Following initial applications of Zoecon RF-437, a gradual reduction in the number of adult pests will be seen over approximately a 1 week period. Reduction in adult populations will be very noticeable within a two week period following continuous application. Due to varying conditions or heavy infestations, the period to expect control may be longer. Since the mode of action of Zoecon RF-437 is to prevent adult emergence, existing adults and pupa present at the time of initial application will complete their life cycle.

As adult suppression peaks, use a maintenance rate of Zoecon RF-437 for continuous protection from population rebound. However, if application of Zoecon RF-437 is halted following population suppression, rebound of the population can be expected within 2 to 3 weeks after stopping application. For continuous suppression throughout the pest season, continue application of Zoecon RF-437.

#### Sludge or Solid Waste Applications

For solid waste applications, use 5 fluid ounces per million gallons of sludge or solids. Apply the dilution until the drying beds have been filled. Following filling of the drying beds, the application of the dilution may be halted. Make applications of the dilution at the <u>influent</u> side as the sludge or solids enter into the drying beds. Application of Zoecon RF-437 to solids will prevent the emergence of adult insect pests thereby keeping infestations under control.]

#### METHODS OF APPLICATION

**Aerial:** Apply Zoecon RF-437 by aircraft to terrestrial locations where mosquito breeding occurs. Use the amount of Zoecon RF-437 listed below in sufficient water to give complete coverage. One-half to 5 gallons of spray solution per acre (4.7 to 46.8 liters/hectare) is usually satisfactory. Do not apply when weather conditions favor drift from areas treated.

**Ground:** Determine the average spray volume used per acre by individual operators and/or specific equipment. Mix Zoecon RF-437 in the appropriate volume of water to give the rate per acre shown below.

[Waste Water Treatment Facilities:] [Dilute Zoecon RF-437 with water prior to use. Apply Zoecon RF-437 with a metering pump, drip bucket or other suitable equipment. Metering pumps are the most efficient and accurate method of application. Appropriate dilution of product will be influenced by the method of application. Depending on the dosage rate, prepare the desired volume of dilution to apply over a {6 – 8 hour period} {24 hour period (day tank)}, or in cases of sludge beds, applied until the beds have been filled. When using delivery devices, it is important to calibrate the device to deliver the required amount of Zoecon RF-437 over a {6 – 8 hour period} {24 hour period}. {Sufficient material may be mixed in advance to provide for applications longer than 24 hours.}][For best results, use metering pumps that are capable of deliverying material for greater than 24 hours.]

#### APPLICATION RATE

**Mosquitoes:** Apply  $^{3}/_{4}$  to 1 fl oz of Zoecon RF-437 per acre (55 to 73 ml/hectare) in water as directed.

#### For Control of Mosquito Larvae Using ULV Application:

Apply at ¾ - 1 fluid ounce per acre. Reapply as breeding sites become reinfested or when monitoring indicates an increase in adult populations.

#### [Waste Water Treatment Pests:]

[Initial Application - 4 - 5 fluid ounces Zoecon RF-437 per 1 million gallons of sewage [waste water] in sufficient water to uniformly apply at the influent side over a 24 hour period.]

[Maintenance Rate - 2.5 - 3.0 fluid ounces Zoecon RF-437 per 1 million gallons of sewage [waste water] in sufficient water to uniformly apply at the influent side over a 24 hour period.]

[To achieve effective results, make initial application rates on a daily basis for 2 weeks without interruption. Use sufficient water/Zoecon RF-437 to achieve uniform application to sewage [waste water] over a 24 hour period. Apply the dilution at the <u>influent</u> side of the particular area to be treated.]

[Maintain initial rate of application for two weeks and then follow the directions for the maintenance rate for continued effectiveness.]

#### [Application to Waste Water - Trickling Filter:

Apply 5 fluid ounces Zoecon RF-437 per 1 million gallons of sewage [waste water] in sufficient water to uniformly apply the material. Apply at times of low periods of flow (typically evening through early morning hours) for 6 – 8 hours. Discontinue treatment during peak flow periods and repeat applications the following day during the low flow period. Continue this application method for 7 to 10 days or until suppression of pests is achieved. Repeat applications every 15 days or as necessary to control pests.]

Fleas: Apply 1 fluid ounce of Zoecon RF-437 per 1000 square feet in water as directed.

#### **APPLICATION SITES**

Pastures: Zoecon RF-437 may be applied after each flooding without removal of grazing livestock.

**Rice**: Zoecon RF-437 must be applied to 2nd, 3rd, and/or 4th instar larvae of mosquitoes found in rice, usually within 4 days after flooding. Zoecon RF-437 treatment may be repeated with each flooding.

**Intermittently Flooded Noncrop Areas**: Apply Zoecon RF-437 as directed above when flooding may result in floodwater mosquito hatch. Typical sites include freshwater swamps and marshes, salt marshes, woodland pools and meadows, dredging spoil sites, drainage areas, waste treatment and settling ponds, ditches and other natural and manmade depressions.

**Crop Areas**: Apply Zoecon RF-437 to irrigated croplands after flooding to control mosquito emergence. Examples of such sites are vineyards, rice fields (including wild rice), date palm orchards, fruit and nut orchards and berry fields and bogs. Irrigated pastures may be treated after each flooding **without** removal of livestock.

**Dense vegetation or canopy areas:** Apply a Zoecon RF-437 sand mixture using standard granular dispersal equipment. For detailed preparation instructions, refer to Guide to Product Application.

For Fleas Outdoors: (1) When using a hose-end sprayer, place 0.75 fluid ounces of Zoecon RF-437 in bottle, add 6 ounces of water and apply at low pressure. (2) Make sure to apply at 0.75 fluid ounces of Zoecon RF-437 per 15 gallons of water. (3) Apply 0.75 fluid ounces of Zoecon RF-437 in 15 gallons of water to every 750 square feet of residential turf. (4) Pay particular attention to areas where pets frequent, such as, in and around dog houses and runs, and around shrubs, outside decks, and porches. (5) If a large population of fleas is present, use [an outdoor flea control product] [brand name of outdoor flea control product] for initial kill of adult fleas.

[Waste Water Treatment Facilities: Apply Zoecon RF-437 to sewage as it <u>flows into</u> trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water facilities where pests are a problem.

Apply Zoecon RF-437 as the sewage enters (influent areas) the targeted processing area. Failure to add the material at the influent side may result in erratic results.]

#### TANK MIXING INSTRUCTIONS:

The user, at his discretion can [tank] mix Zoecon RF-437 with a registered adulticide or other larvicide, such as *Bacillus thuringiensis*, variety *israeliensis* (*B.t.i.*) or *Bacillus sphaericus* (*B.s.*) unless the tank mix product label prohibits such mixing. Use of the resulting tank mixture must be used in accordance with the more restrictive label limitations and precautions.

**CHEMIGATION:** Refer to supplemental labeling entitled "Guide to Product Application" for use directions for chemigation. Do not apply this product through any irrigation system unless the supplemental labeling on chemigation is followed.

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide Storage: Store in a cool place, away from other pesticides, food and feed. In case of leakage or spill, soak up with sand or another absorbent material. Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Container Handling: Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptyng. Triple rinse as follows. Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

For information, call 1/800-248-7763 or visit our Web site: www.altosid.com .

Wellmark International 1501 East Woodfield Road 200W Schaumburg, IL 60173

Made in USA

#### ZOECON RF-437 MOSQUITO GROWTH REGULATOR SR-20

#### PREVENTS EMERGENCE OF ADULT FLOODWATER MOSQUITOES

#### GUIDE TO PRODUCT APPLICATION

#### FOR THE FIRST TIME USER

ZOECON RF-437 MOSQUITO GROWTH REGULATOR SR-20 (SR-20) is the result of extensive research into the intricacies of natural biochemical and physiological development of insects. New chemical technology and biological findings were combined to develop a unique mosquito larvicide.

SR-20, an insect growth regulator (IGR), acts by inducing morphological changes which interfere with normal development. These effects, not immediately apparent, result in the failure of adult mosquitoes to emerge from pupae. SR-20 is <u>not</u> a conventional pesticide. It does not produce the nondiscriminatory rapid, directly toxic effects that are associated with traditional larvicides. SR-20 differs from other larvicides you may have used only in the manner and time course of its action after application.

SR-20 is applied to second, third or fourth instar larvae using standard larviciding equipment in a manner similar to other larvicides. After application to second, third or fourth instar larvae at recommended rates, absolutely no effects on larvae will be observed. They will continue developing normally and will pupate. Pupae will appear unaffected, but will eventually die. Adults will not emerge. Infrequently, a few adults may be seen at the water surface but they will have abnormalities preventing flight and will not survive. Because the effect of SR-20 is neither larval death nor widespread mortality immediately following pupation, the number of adults which emerge is the only criterion for accurately assessing control. Checks by dip counts during larval and pupal stages will give no measure of effectiveness.

Refer to the following diagram and checklist, in addition to label instructions for guidance in timing of application and performance evaluation. They will assist you in obtaining the best possible results with this unique product.

Wellmark International 1501 East Woodfield Road 200W Schaumburg, IL 60173

For information, call 1/800-248-7763

The information presented herein, while not guaranteed, is to the best of our knowledge true and accurate. No warranty or guarantee, express or implied, is made regarding the performance or stability of any product, since the manner of use and conditions of storage and handling are beyond our control.

#### **CHECK LIST**

Things to remember when using SR-20

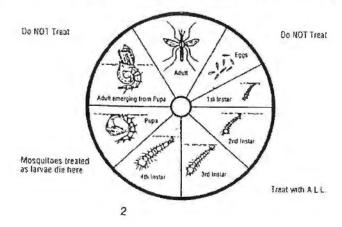
#### DO the following:

- 1. DO treat second, third and/or fourth instar larvae, not pupae or adults. (First instar larvae are so small they are not readily detectable.)
- DO wait until treated larvae have pupated. Then <u>collect pupae</u> and transfer to laboratory to observe for emergence of adults.
- 3. DO observe pupae for several days, since death of IGR treated mosquitoes occurs when pupae would normally emerge as adults. (Careful observation is necessary since dead pupae decompose rapidly and thus are not easily seen.)
- 4. DO monitor emerging adults at the treatment site. This absolutely requires that emergence traps be placed in treatment areas to capture adult mosquitoes as they emerge.

#### DO NOT do the following:

- DO NOT take dip counts of larvae after treatment for the purpose of performance evaluation.
   Normal looking larvae will be present.
- DO NOT take dip counts of pupae after treatment for the purpose of performance evaluation.
   Normal looking pupae will be seen but these will not develop into normal adults.
- 3. DO NOT think SR-20 has failed if some adult mosquitoes are flying in treated areas; they probably have flown in from nearby untreated areas. Numbers 2 and 4 of the "DO" checklist are the only methods of accurately assessing effectiveness.
- 4. DO NOT spray again, either with SR-20 or a conventional insecticide, because larvae or pupae are present after application. This is normal. The effectiveness of SR-20 can only be measured by lack of adult emergence.

## LIFE CYCLE OF MOSQUITO WHEN TO APPLY ZOECON SR-20 MOSQUITO GROWTH REGULATOR



#### Preparation of ALTOSAND® Granular Formulation

#### An "On-Site" Method of Preparing a Granular Formulation of SR-20

#### INTRODUCTION

A method of application of SR-20, using sand as a carrier, has been developed for use in floodwater mosquito breeding areas with dense vegetation or canopy. The characteristics of ALTOSAND provide excellent foliage penetration, insuring that the active ingredient reaches the water where it is released from the sand.

ALTOSAND will prevent the emergence of species of the floodwater mosquito complex when applied to second, third or fourth larval instars at a rate of ten to thirteen pounds per acre.

#### **PREPARATION INSTRUCTIONS**

The following materials are required to prepare a 100 lb. batch of ALTOSAND:

99 lb washed, dry sand (20-45 mesh) 0.5 lb SR-20 (15 fluid oz/lb) 0.5 lb HiSil 233 (silicon dioxide) Small Funnel Cement Mixer

- Measure the time required for a level funnel full of sand to empty.
- 2. Into a rotating-type mixer, place 99 lb of dry (20-45 mesh) sand. While the mixer is rotating, slowly pour 0.5 lb (7.5 fl oz) of SR-20 onto the sand. (If better wetting is required, SR-20 may be diluted in up to an equal volume of water.)
- 3. Mix until the sand is uniformly coated with SR-20 (usually 5 to 10 minutes).
- 4. Stop the mixer and add 0.5 lb of HiSil 233. Cover the mixer to reduce dust. Start the mixer and run for approximately 5 minutes. (The quantity of HiSil 233 necessary to achieve a dry, free-flowing mixture will vary depending on the particle size distribution and moisture of the sand.)
- 5. Compare the flow rate of the ALTOSAND mixture with that of untreated sand in Step No. 1. Add more HiSil if it flows significantly slower and reduce the amount of HiSil in subsequent batches if the mixture flows at the same or a faster rate and is excessively dusty.

#### APPLICATION RATE AND METHODS

Apply at a rate of 10 to 13 lb of the final mixture per acre, using standard granular dispersal equipment.

**Chemigation:** Apply this product only through flood (basin), furrow or border irrigation systems. Do not apply this product through any other type of irrigation system. Crop injury, lack of effectiveness or illegal pesticide residues in the crop can result from nonuniform distribution of treated water. If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Flood (Basin), Furrow and Border Chemigation: Systems using a gravity flow pesticide dispensing system must meter the pesticide into the water at the head of the field and downstream of a hydraulic discontinuity such as a drop stucture or weir box to decrease potential for water source contamination from backflow if water flow stops.

Systems utilizing a pressurized water and pesticide injection system must meet the following requiremments:

- \* The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
- \* The pesticide injection pipeline must contain a functional, automatic quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- \* The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- \* The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- \* The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where the pesticide distribution is adversely affected.
- \* Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

A pesticide supply tank is recommended for the application of SR-20 by chemigation.

ALTOSAND is a registered trademark of Wellmark International.

EPA Reg. No.: 2724-446

#### **ZOËCON® RF-437 MOSQUITO GROWTH REGULATOR SR-20**

Supplemental Labeling

FOR CONTROL OF MOSQUITO LARVAE USING AERIAL ULV APPLICATION AND UPDATED TANK MIXING DIRECTIONS FOR USE

EPA Reg. No. 2724-446

#### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Read the label affixed to the container for Zoëcon® RF-437 Mosquito Growth Regulator SR-20 before using.

#### Important

Use of Zoëcon® RF-437 Mosquito Growth Regulator SR-20 according to this labeling is subject to the use precautions and limitations imposed by the label affixed to the container for Zoëcon® RF-437 Mosquito Growth Regulator SR-20.

#### For Control of Mosquito Larvae Using Aerial ULV Application:

For aerial application to terrestrial sites, apply at the rate of ¾ - 1 fluid ounce of product per acre to water-holding containers and other small bodies of water that breed mosquitoes. Use equipment capable of applying a fine mist or ULV. Follow equipment manufacturer's recommendations when making applications. Direct spray applications to sites where mosquitoes breed. These sites include tires and tire piles, potted plants, tree holes, garbage bins, cans, birdbaths, rain barrels, and other water-holding containers and small bodies of water. Reapply as breeding sites become reinfested or when monitoring indicates an increase in adult populations.

Tank Mixing Instructions:

The user, at his discretion can [tank] mix **Zoecon RF-437 Mosquito Growth Regulator SR-20** with a registered adulticide or other larvicide, such as *Bacillus thuringiensis*, variety *israeliensis* (*B.t.i.*) or *Bacillus sphaericus* (*B.s.*) unless the tank mix product label prohibits such mixing. Use of the resulting tank mixture must be used in accordance with the more restrictive label limitations and precautions.

For information or in case of emergency, contact 1-800-248-7763.

This labeling must be in the possession of the user at the time of application.

Zoëcon is a registered trademark of Wellmark International.

#### Registrant:

Wellmark International

1501 East Woodfield Road 200W Schaumburg, Illinois 60173 www.altosid.com

This supplemental label expires on September 29, 2019 and must not be used or distributed after this date.

09/29/2016

strete the Feder's insented in Europoids and Roderds on Act as arranded for the postude registered under

EPA Reg No 2724-446

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#### DEFU OIG ACTIVE INGREGIENT CHECKLIST

### New Pr | ict Registration/Existing Product | nendment

Fast Track □ PRIA Actions B650 □, B660 □, B670 □, B680 X, B710□, ∠/20 □, B730 □, B880 □ & B900 □

EPA Reg. No.: 2724-446

RAL:

Menyon Adams

Application Date: May 26, 2016

#	Check list Item	Yes	No
1.	Application Form (EPA Form 8570-1) - signed & complete including package type? IF NO, STOP! Call applicant and have them correct application and resubmit.	x	
2.	If amendment, was <b>final printed labeling</b> received for previous action? <b>IF NO, STOP!</b> E-mail applicant and request final printed labeling.	X	
3.	Confidential Statement of Formula (CSF) EPA Form 8570-4 Basic Formula X Alternate Formula	(s) X	
a.	CSF Review completed? IF YES, SKIP to ITEM 4.		X
b.	CSF is signed and dated? IF NO, CALL APPLICANT.	1	X
c.	Completely filled out: CAS numbers, pH, flashpoint, flammability, if applicable?		X
d.	Are the totals accurate?		X
e.	Certified limits agree with 40 CFR 158.175? Note that if preliminary or 5 batch analysis differ from Section 158.175(b), limits based on batch analysis would need to be proposed under Section 158.175(c).		X
f.	Viability (if live microbial, i.e., cfu/gram)?		
g.	PC codes assigned on CSF for actives & inerts plus 40 CFR 180.910, 180.920, and 180.930 codes noted for products that have food or feed uses?		Х
h.	List I inert ingredient(s) present in the formulation? If YES, be sure it is listed on the label.		X
i.	Alternate formula(s) do not require different labeling from basic CSF or other alternate CSFs per 40 CFR 152.43(b)(3).		
j.	Source for a.i. is a registered pesticide? (When a proposed alternate or new basic formula involves a new registered manufacturing-use product as the active ingredient source it must be determined whether the manufacturing-use products used to formulate are similar enough to warrant use of existing product specific data such as acute toxicity.)	X	
k.	Does CSF list peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, or wheat commodities? <b>If YES</b> , RAL must evaluate label directions for compliance with 40 CFR 180.1071.		Х
4.	Data and Data Matrix present. (EPA Form 8570-35)	x	
a.	a) Using Selective Method? [IF NO, SKIP to ITEM 5 since data matrix required for selective method.]	Х	
b.	Complete Data Matrix supporting both the product registration and, if applicable, the proposed amendment. Minimum Data Matrix for registration includes: product specific acute toxicity, product chemistry, and efficacy data for public health pests claimed on label.		
c.	Adequate product specific data submitted?	X	
d.	Registered source used for active ingredient? IF YES, SKIP to ITEM 5. (If active ingredient is from a registered source (manufacturing-use product), generic data should be satisfied by registered source.) If NO or if use not supported by registered source, generic data is necessary.	х	
e.	Data passed PR Notice 86-5 for formatting and MRID number assignment?		
f.	Public copy of Data Matrix provided? (PRN 98-5)		
5.	Certification with Respect to Citation of Data (EPA Form 8570-34): See 40 CFR 152.80-98 and P [Note: If no data are required or submitted, form is not needed. This is often true for minor amendments.]	R Notice	98-5
a.	Did applicant check a Method of Support?	x	
o	General Offer to Pay checked for Cite-all Method or Cite-all under Selective Method?	x	
· .	Is the form signed and dated?	X	
i.	Check form and Data Matrix; are Exclusive Use data cited from other sources?		X
e.	IF YES, is the required authorization letter included in application?		
). 	Formulators Exemption (EPA Form 5870-27)		
	If registrant is using a registered source active ingredient in the formulation (manufacturing-use		

	product), is form thick out completely and signed:		-
#	Check list Item	Yes	No
7.	Exclusive Use Notice Requirement Prior to Registration (Required per 40 CFR 152.116, separate from permission of an exclusive use data submitter to rely on exclusive use data)		х
	Is this an exclusive use active ingredient or mix of active ingredients (registered w/in last 10 yrs)?  If YES, go to a) or b) below.		
a.	a) Has a notification of intent to register letter or email been sent to the exclusive use data submitter(s) at least 30 days before registration? (This notification is required for all methods of data support except when the exclusive use data submitter(s)' product is used to formulate and the formulator's exemption is claimed.)		X
b.	Has exclusive use data submitter requested during 30 day period the applicants' list of data requirements and method of compliance?		х
c.	Has registrant submitted certification from exclusive use data submitter that submitter is aware of the application and does not object to the registration?		X
8.	Science Review completed? Comments:	X	
9.	Label(s) Review Menyon Adams <u>Date of Label Review: September 23, 2016</u>		
a.	Label(s) in conformance with current Label Review Manual and appropriate REDS.	х	
b.	Labeling statements and claims are supported by Acute Toxicity, Product Chemistry data (or acceptable waivers).  Acceptable efficacy studies support public health pests claimed on label.	X	
C.	Nominal concentration of active ingredient shown in ingredients statement.	X	
d.	Viability included as sub-statement of Ingredient Statement (if live microbial, i.e., cfu/gram).		
e.	Storage and disposal instructions agree with container types listed on application form.		
f.	Unique Product Name for Same Company (Check OPPIN).	X	
g.	Does CSF list peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, or wheat commodities? <b>If YES</b> , RAL must evaluate label use directions for compliance with 40 CFR 180.1071.		х
h.	Does label bear "National Organic Program" (PR Notice 2003-1) or OMRI claims?		X
	If YES, National Organic Program or OMRI claims approved by Chris Pfeifer?  NA □		
i.	Labeling is acceptable. Corrections or changes are NOT necessary.	X	
j.	Are DERs attached? NA		
k.	Comments:		



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

#### OFFICE OF CHEMICAL SAFETY AND POLUTION PREVENTION/OFFICE OF PESTICIDE PROGRAMS

#### MEMORANDUM

DATE:

Sept. 20, 2016

SUBJECT:

Science review in support of label amendment to add aerial ultra-low volume (ULV) spray applications to the labels of Altosid Liquid Larvicide Mosquito Growth Regulator (SR5) and Zoecon RF -437 Mosquito Growth Regulator (SR20) products, containing 5% and 20 % w/w (S)- Methoprene, respectively, as

their active ingredient.

Decision Number:

986966

986968

**EPA File Symbol Number:** 

2724-446 and 2724-392

Chemical Class:

Biochemical

PC Code:

105402

CAS Number:

65733-16-6

**Active Ingredients:** 

(S)-Methoprene

**Tolerance Exemptions:** 

Non-food

MRID Numbers:

499355-01

FROM:

Clara Fuentes, Ph.D.

Entomologist

Biochemical Pesticides Branch

Biopesticides & Pollution Prevention Division (7511P)

THROUGH: Russell Jones, Ph.D.

Senior Scientist

Biochemical Pesticides Branch

Biopesticides & Pollution Prevention Division (7511P)

TO:

Menyon Adams, Regulatory Action Leader

Biochemical Pesticides Branch

Biopesticides & Pollution Prevention Division (7511P)

#### **ACTION REQUESTED**

Wellmark International is submitting efficacy data in MRID 499355-01 in support of label amendment to add aerial ULV application to the labels of Altosid Liquid Larvicide Mosquito Growth Regulator (SR5), and Zoecon RF -437 Mosquito Growth Regulator (SR20) products,

#### RECOMMENDATIONS AND CONCLUSIONS

Product Performance: Acceptable.

MRID 499355-01; Acceptable. The study shows that under the conditions of the test, the efficacy of the product ranges between 90 and 70 % average Emergence Inhibition. The study was conducted using SR5 (5%), EPA Reg. No. 2724-392 product, but the data is applicable to SR20 (20%) (EPA Reg. No. 2724-446, because both products were adjusted to be applied at the same rate (Refer to Calculations to adjust same application rate, below). The conditions of the test support the proposed label recommended rate and mode of application for control of mosquito larva using ULV aerial application. Data showed that wind speed variation influences the efficacy of the larvicide application. When average wind speeds fell below 1 mph (between 2.4 and 0 mph) average percent emergence inhibition (E.I.) decreased to 70 % (adjusted with Abbott's formula for control mortality = 4.7 %). Average percent E.I. = 70% ranged between 100 and 20 %. At wind speeds between 5 - 1 mph, average percent E.I. were 91 and 88 % (adjusted with Abbott's formula for control mortality = 2.5 and 12%, respectively). Average percent E.I. = 91 and 88 %, ranged between 100% and 67 %, and 100 and 70 %, respectively. Furthermore, data on *Aedes albopictus* supports label claim that the product is effective against Zika vector.

1) The registrant adequately explains that the rate per acre is adjusted for the difference in concentrations of active ingredient in each product to attain at the same rate of application, 0.010 or 0.013 lb / Acre, as tabulated below:

#### Calculations to ad ust same application rate:

End use rate for 2724-392

Percent A.I.	lb A.I. / gallon concentrate.	Rate per acre (fl. oz.)	lb per acre
5%	0.43	3 (low)	0.010
5%	0.43	4 (high)	0.013

End use rate for 2:24-466

Percent A.I.	lb A.l. / gallon concentrate.	Rate per acre (fl. oz.)	lb per acre
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Percent A.I.	lb A.I. / gallon concentrate.	Rate per acre (fl. oz.)	1b per acre
20%	1.72	0.75 (low)	0.010
20%	1.72	I (high)	0.013

2) In addition, label language for application instructions have been upgraded as follows:

"For aerial application to terrestrial sites, apply by fixed wing or rotary aircraft. Apply at the rate of 3 – 4 fluid ounces of product to acre diluted with water at a minimum of a 1:1 mix ratio with water. Apply using ULV equipped and capable aircraft. Unlike ULV sprays targeting flying mosquitoes, it is important that spray droplets deposit in targeted areas. Target terrestrial areas where mosquitoes breed. These sites include tires, open containers, garbage bins, birdbaths, and gutters, which hold small amounts of water. Spray equipment must be adjusted so that the volume median diameter (VMD) produced ranges from 60 microns ( $Dv0.5 < 60\mu$ ) to 100 microns ( $Dv0.5 < 100\mu$ ), and that 90% of the spray is contained in droplets smaller than 200 microns ( $Dv0.9 < 200\mu$ ). Directions from the equipment manufacturer or vendor, pesticide registrant, or test facility using a wind tunnel and laser-based measurement instrument must be used to adjust equipment to produce acceptable droplet size spectra. Application equipment must be calibrated annually to confirm that nozzle flow rate(s) are accurate. Do not apply at altitudes below 100 feet unless using unmanned aircraft designed for low application heights. Apply when wind speed on the ground is  $\geq 1$  mph and  $\leq 10$  mph. Apply when wind factors promoting drift are low. For best results, use Global Positioning System (GPS) equipped aircraft."

#### STUDY SUMMARY

The objective of the study was to assess the effectiveness of Altosid Liquid Larvicide Mosquito Growth Regulator (SR5) when applied by ultra low volume (ULV). The product was tested at the lowest rate of application, 0.010 lb / Acres (3 fl oz. of active ingredient / Acre), using aerial ULV, target VMD > 60 microns. The target mosquito specie was Asian Tiger Mosquito, *Aedes albopictus*.

#### Experimental design and data analysis:

#### Application rate and Equipment:

A 1:1 water dilution of the product was applied by helicopter at the lowest application rate of 3 fl. oz. per acre. Nozzles were adjusted for 1,000 RPM; VMD was approximately 80 microns (droplet size), and flow rate was 142 fl. oz. / min. Each application consisted of 4 swaths from an altitude 100 ft above ground and flight speed of 60 MPH. Each swath covered 200 ft (swath width).

#### Application site:

The layout of the application site consisted of a 3 X 3 grid within an area of 300 sq. ft (200' L X 100' W). Nine treated sampling stations were marked with surveyors flags within the 200' L X 100' W application grid. Sampling stations were positioned to form 2 columns at opposing edges of the grid, and one column down the middle of the grid, for a total of 3 columns. Columns were approximately 50 feet apart and rows were approximately 100 feet apart in straight lines. Nine control sampling stations were setup outside the treatment grid in a column with 10 feet spacings. The droplet deposition assay consisted of 3 applications at different environmental conditions, each having 3 replicated sets of treated and control droplet collection samplers.

#### Droplet collection samples:

A food grade red dye was added to the larvicide solution for determination of droplets deposition. Droplet samples were collected on Parafilm squares placed on 90 mm DIA X 20 mm H Petri-dish to collect aerosolized larvicide droplets that impinged in the application area. The Parafilm squares were paired with a Kromekote cards at a grid sampling site that contained 9 sampling sites. The Kromekote card served as a qualitative measurement of droplets impinging in the grid. Following application, Droplet collection samples were sent to the lab in refrigerated packaging and stored in a freezer. They were removed from frozen storage 1 -2 hours prior to placement in mosquito breeding containers.

#### Larvicide testing:

The larvicide treatments were conducted in 3 series, modeling the 3 field applications. Nine treated replications and 9 non-treated replications were conducted simultaneously. Each replication contained 10 (2<sup>nd</sup> and 3<sup>rd</sup> Instar) *Aedes albopictus* larvae. The larvicide testing was conducted employing mosquito breeding containers of 16 oz. and 32 oz. capacity under laboratory conditions. Droplet collection Parafilm wax were placed in the bottom of the mosquito breeding containers. A volume of 164 ml dechlorinated water was added to each mosquito breeder. This water volume is equal to approximately 17 ml of water per square inch of droplet collection substrate (9.16 square inches) (approximately equal to a soft drink can half full). In addition, 1.5 ml of a 10% liver powder / water dilution was added as a food source to each breeding container. There were 10 breeding containers per replication. Observations were conducted after all pupae either emerged or died.

Efficacy was evaluated based on the test substances ability to prevent mosquito larvae from developing into adult mosquitoes. When emergence was complete, the number of dead pupae (DP), dead adults on the water surface (DA), and live adults (AA) in each container were recorded and percent emergence inhibition for each treatment application was calculated as follows:

Percent emergence inhibition (E.I.) =  $(DP + DA) / (AA + DA + DP) \times 100$ 

During the observation, close examination of adult mosquitoes that seemed to have emerged but were laying on the surface of the water was conducted. These adults were examined for evidence of attachment to the exuvia. If evidence was present, the adult was counted as a dead adult. Abbott's formula was used to adjust percent control when untreated control mortality was high.

#### Results:

Treatment 1: A 1:1 dilution of Altosid Liquid Larvicide 5% and water was applied at a rate of 3 ounces per acre from a helicopter at the speed of 60 mph at an altitude of 100 feet. The average wind speed was 3.61 mph; average temperature, 82°F, and relative humidity was 74%. The wind was light and variable with an average airspeed of 3.61 mph with highs speeds up to 5 mph and lows speeds down to 1 mph. The average percent E.l. ranged from 100% to 67%, the average percent E.l. corrected with Abbott's formula was 88%. The non-treated control mortality was 12%.

Treatment 2: A 1:1 dilution of Altosid Liquid Larvicide 5% and water was applied at a rate of 3 ounces per acre from a helicopter at the speed of 60 mph at an altitude of 100 feet. The average wind speed was 2 mph; average temperature, 81 "F, and relative humidity was 76%. The wind was light and variable with an average airspeed of 2 mph with highs speeds up to 3.3 mph and lows speeds less than 1 mph. The average percent E.I. ranged from 100% to 70%, the average percent E.I. corrected with Abbott's formula was 91%. The non-treated control mortality was 2.5%.

Treatment 3: A 1:1 dilution of Altosid Liquid Larvicide 5% and water was applied at a rate of 3 ounces per acre from a helicopter at the speed of 60 mph at an altitude of 100 feet. The average wind speed was 0.9 mph, average temperature, 81 °F: and relative humidity 77%. The wind was light and variable with an average airspeed of 0.9 mph with highs speeds up to 2.4 mph and lows speeds 0 mph. The average percent E.I. ranged from 100% to 20%, the average percent E.I. corrected with Abbott's formula was 70%. The non-treated control mortality was 4.7%.

#### Conclusion:

Data showed that wind speed variation influences the efficacy of the larvicide application. At wind speeds between 5 - 1 mph, average percent E.I. were 91 and 88 % (adjusted with Abbott's formula for control mortality = 2.5 and 12%, respectively). Average percent E.I., 91 and 88 %, ranged between 100% and 67 %, and 100 and 70 %, respectively. Data showed that as average wind speeds fell below 1 mph (between 2.4 and 0 mph) average percent E.I. decreased to 70 % (adjusted with Abbott's formula for control mortality = 4.7 %). Average percent E.I. ranged between 100 and 20 %.



#### Nancy Huebl

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#### Wellmark International

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May 26, 2016

Document Processing Desk (AMEND)
Office of Pesticide Programs 7504P
U.S. Environmental Protection Agency
Room S-4900 One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

ATTENTION:

Linda Hollis/BPPD Branch Chief

SUBJECT:

SUPPLEMENTAL LABEL AND LABEL AMENDMENT TO ADD LANGUAGE FOR AERIAL ULV APPLICATION FOR CONTROL OF MOSOUITO LARVAE AND

TO UPDATE TANK MIX DIRECTIONS FOR USE FOR

ALTOSID® LIQUID LARVICIDE (SR5)/EPA REG. NO. 2724-392 AND

ZOËCON® RF-437 MOSOUITO GROWTH REGULATOR SR20/EPA REG. NO. 2724-446

#### Dear Ms. Hollis:

Enclosed please find an efficacy study to support label amendments to add aerial ULV application. Aerial application has been approved since initial approved labels ('85/'90). The addition of the aerial application to the ULV use is to take advantage of recent concern with Dengue and Chikungunya cases in Florida and other southern states as well as the Zika threat concern. In February, a 2ee was approved for this use in Florida. Mosquito vectors for these diseases are container breeders and mosquito abatement districts have a difficult time treating for these mosquitoes so ULV application from aircraft will help to treat for these mosquitoes. The efficacy study was done using the SR5 (5%) 2724-392 product but the data are also applicable for the SR20 product. Additionally, the tank mix directions for use were revised to reflect current practices. In order that this application can be used in the field promptly upon EPA amendment approval, please stamp approve the enclosed supplemental labels (and provide expiration date). Additionally, included are completed EPA Form 8570-1, a clean copy of revised labeling and one highlited label copy for your convenience in viewing where changes were made (red is new text, blue strikethrough is deleted text).

Because these label amendments are supported by efficacy data submission, they are being submitted as a PRIA R340 action which has a fee of \$3,988 and a four month review time. A payment in that amount has been submitted via Pay.gov and a payment receipt is enclosed.

The following documentation is included with this submission:

- 1. Application for Registration Form (EPA Form 8570-1)
- 2. Data Matrix (EPA Form 8570-35)
- 3. Certification with Respect to Citation of Data (EPA Form 8570-34)
- 4. Transmittal Document for 1 efficacy study submitted
- 3 copies of efficacy study: Efficacy of Altosid Liquid Larvicide Mosquito Growth Regulator When Applied by ULV
- 6. Copies of amended labels (1 clean, 1 with highlighted changes)
- 7. Receipt of Payment of PRIA Fee

May 26, 2016

Document Processing Desk (AMEND) Office of Pesticide Programs 7504P U.S. Environmental Protection Agency Room S-4900 One Potomac Yard 2777 South Crystal Drive Arlington, Virginia 22202-4501

ATTENTION: Linda Hollis/BPPD Branch Chief

SUBJECT: SUPPLEMENTAL LABEL AND LABEL AMENDMENT TO ADD LANGUAGE

FOR AERIAL ULV APPLICATION FOR CONTROL OF MOSQUITO LARVAE AND

TO UPDATE TANK MIX DIRECTIONS FOR USE FOR

ALTOSID® LIOUID LARVICIDE (SR5)/EPA REG. NO. 2724-392 AND

ZOËCON® RF-437 MOSQUITO GRQWTH REGULATOR SR20/EPA REG. NO. 2724-446

If you have any questions please, call me directly at 847-330-5376. Thank you for your assistance in this matter.

Yours sincerely,

WELLMARK INTERNATIONAL

Mancy Shield

Nancy Huebl

Senior Registration Specialist

nhuebl@central.com

enclosure

#### TRANSMITTAL DOCUMENT

#### NAME AND ADDRESS OF SUBMITTER

Wellmark International 1501 E. Woodfield Road, Suite 200W Schaumburg, IL 60173

#### REGULATORY ACTION SUPPORTED BY THIS SUBMISSION

Submission of Efficacy Study (Mosquitoes) to Support a Label Amendment for Altosid® Liquid Larvicide/EPA Reg. No. 2724-392 and Zoëcon® Rf-437 Mosquito Growth Regulator/EPA Reg. No. 2724-446

#### TRANSMITTAL DATE

May 2016

#### LIST OF SUBMITTED STUDIES

Volume 1 of 1. Central Life Sciences and Manatee County Mosquito Control, December 2015.

Efficacy of Altosid Liquid Larvicide Mosquito Growth Regulator When Applied by ULV, Wellmark International Study No. 4956, 50 pages

COMPANY OFFICIAL: Nancy Huebl

Nancy Huebl
Senior Registration Specialist

COMPANY NAME: Wellmark International

COMPANY CONTACT: Nancy Huebl (847) 330-5376

#### Adams, Menyon

From: Nancy Huebl <NHuebl@central.com>
Sent: Monday, August 01, 2016 2:07 PM

To: Adams, Menyon

Cc: Fuentes, Clara; Heather Friedli; Steve Spaulding Subject: RE: Registration #s 2724-392 and 2724-446

Attachments: epa amend aerial ulv tank mix aerial dfu 816.pdf; epa amend aerial ulv tank mix aerial dfu

clean 816.pdf; EPA amend aerial ulv tank mix aerial dfu 816.pdf; EPA amend aerial ulv tank

mix aerial dfu clean 816.pdf

Menyon, I am attaching labels for 2724-392 and 2724-446 with language added per your request below regarding nozzle type and droplet size (hilited and clean copies). The tables below should address your question about label rate equivalency.

#### End use rate for 2724-392

Percent A.I.	lb A.I. / gallon concentrate.	Rate per acre (fl oz)	lb per acre
5%	0.43	3 (low)	0.010
5%	0.43	4 (high)	0.013

#### End use rate for 2724-466

Percent A.I.	lb A.I. / gallon concentrate.	Rate per acre (fl oz)	lb per acre	
20%	1.72	0.75 (low)	0.010	
20%	1.72	1 (high)	0.013	

Let me know if you have any additional questions. Nancy Huebl 847-330-5376

From: Adams, Menyon [mailto:Adams.Menyon@epa.gov]

Sent: Wednesday, July 27, 2016 2:42 PM
To: Nancy Hueb! <NHuebl@central.com>
Cc: Fuentes, Clara <Fuentes.Clara@epa.gov>
Subject: Registration #s 2724-392 and 2724-446

#### Good Afternoon.

The data that you have on file is fine. However, additional information is needed in support of the proposed changes. Specifically, information that include the nozzle type and optimal droplet size on the label use instructions. All is needed is to add that information on the label.

Second, you proposed to bridge data from 2724-392 to product 2724-446. Product 2724-392 contains 5% a.i. product 2724-446 contains 20% of the same a.i. (2427-446 is a concentrate formulation). To bridge data from 2427-392 to 2724-446, the application rates should be equivalent for both products. I need for you to send calculations showing that application rates for 2724-392 and for 2724-446 stated on the label are equivalent.

This information can be sent to me directly via email.

Best Regards,

Menyon Adams, Biologist
U.S. Environmental Protection Agency
Office of Pesticide Programs (7511P)
Biopesticides and Pollution Prevention Division (BPPD)
Biochemical Pesticides Branch (BPB)
adams.menyon@epa.gov
703-347-8496 (office)
703-305-0188 (fax)

http://www.epa.gov/pesticides/



Disclaimer: This communication and any attachments contain private, confidential, privileged and/or proprietary information intended solely for the Recipient(s) named above. If you are not the intended Recipient, any use, dissemination, distribution or copying of the communication is strictly prohibited. If received in error we apologize and ask that you please notify the Sender by returning this e-mail and permanently deleting this communication from your computer, including destruction of any printed copies. Any views expressed herein are not necessarily those of the Company represented by this e-mail source. No contracts, agreements or legally binding understandings may be entered into solely by an e-mail communication.

Section - II   Part arrest tables in response to figure failed and section I.)	Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95					
Compare/Product Number   Number   N	Environmental Protection A	Agency	X Amendment	OPP Identifier Number		
Vicilinaris International/2724-46   Unit   Vicilinaris International/2724-46   Vicilinaris International/20ccon RF-437 Mosquito Growth Regulator (Regulator (Regulator (Regulator (Regulator SR-20   Vicilinaris International 20ccon RF-437 Mosquito Growth Regulator (Regulator (Regulator Regulator (Regulator Regulator Regulato	Applicatio	n for Pesticide - Section I				
Section - III	Wellmark International/2724-446 4. Company/Product (Name)	Linda Hollis				
Section - II    Amandment - Explain below.	Regulator SR-20  5. Name and Address of Applicant / Registrant (Include ZIP Code)  Wellmark International  1501 East Woodfield Road, Suite 200W  Schaumburg, Illinois 60173	6. Expedited Review. (b)(i), my product is similar EPA Reg. No.				
Amendment - Explain below.	Check it this is a new address					
Resubmission in response to Agency letter dated   "Me Too" Application   The Too Too Too Too Too Too Too Too Too To		Section - II	THE RESERVE THE SECOND STREET			
Label amendment plus supplemental label to add aerial application to ULV applications (efficacy data included) and update tank mixing directions. This is a PRIA R340 action, fee of \$3,988 with 4 months review time    Section - III	Resubmission in response to Agency letter dated	Agency lette	er dated optication			
1. Material This Product Will be Packaged In: Child-Resistant Packaging Ves No If Yes No If Yes If Y	Label amendment plus supplemental label to add aerial application to U	LV applications (efficacy data inc	eluded) and update tank mi	xing directions. This is a PRIA		
Child-Resistant Packaging Unit Packaging Yes		Section - III				
6. Manner in Which Label is Affixed to Product  Section - IV  1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)  Name Nancy Huebl  Certification  I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete 1 acknowledge that any knowingly false or misleading statements my be punishable by fine or imprisonment or both under applicable law  3. Title Senior Registration Specialist  A any Austh  3. Title Senior Registration Specialist  4. Typed Name  5. Date	Child-Resistant Packaging  Yes  X No  If "Yes Unit Packaging Will No. per container Packaging wgl Container Packaging wgl Submitted  3. Location of Net Contents Information 4. Size(s) Retail Container Packaging wgl Submitted	Yes No Yes Unit No per container	Metal X Plastic Glass Paper Other (Specil	(y)		
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)  Name  Title  Nancy Huebl  Certification    certify that the statements I have made on this form and all attachments thereto are true, accurate and complete acknowledge that any knowingly false or misleading statements my be punishable by fine or imprisonment or both under applicable law  2. Signature  Manay Much  Senior Registration Specialist  3. Title  Senior Registration Specialist  5. Date	6 Manner in Which Label is Affixed to Product  Lithograph  X Paper glue	d 🕒		ying Product		
Name Name Name Name Tille Senior Registration Specialist  Certification    certify that the statements I have made on this form and all attachments thereto are Irue, accurate and complete I acknowledge that any knowingly false or misleading statements my be punishable by fine or imprisonment or both under applicable law  2 Signature    Agray   August   Senior Registration Specialist	The second of th			*		
Certify that the statements I have made on this form and all attachments thereto are true, accurate and complete 1 acknowledge that any knowingly false or misleading statements my be punishable by fine or imprisonment or both under applicable law  2 Signature    3 Title   Senior Registration Specialist	Name Tille Nancy Huebl Seni	or Registration Specialist	Telephon	e No. (Include Area Code) -5376		
Manay Wulle Senior Registration Specialist  4. Typed Name 5. Date	I certify that the statements I have made on this form and all attachr acknowledge that any knowingly false or misleading statements my	ments (hereto are Irue, accurate and		Received		
4. Typed Name 5. Date	L Digitalian / A					
	4. Typed Name 5. Da					



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 1200 Pennsylvania Avenue, N.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration

and 0.25 hours per response for reregistration and special review activities, including time for recomments regarding burden estimate or any other aspect of this collection of information, including Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avento this address.	eading the instruction iding suggestions for	s and completing the necessary forms. Send reducing the burden to: Director, Collection			
Certification with Respect to C	itation of Data				
Applicant's/Registrant's Name, Address, and Telephone Number Wellmark International 1501 E. Woodfield Rd., Ste. 200W, Schaumburg, IL 60173; 847-330-5380		EPA Registration Number/File Symbol 2724-446			
Active Ingredient(s) and/or representative test compound(s) S-Methoprene		Date May 26, 2016			
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)  Aquatic Food, Aquatic Non-crop, Commercial and Industrial  Product Name  Altosid Liquid Larvicide					
NOTE: If your product is a 100% repackaging of another purchased EPA-registers submit this form. You must submit the Formulator's Exemption Statement (EPA Form		or all the same uses on your label, you do not need to			
I am responding to a Data-Call-In Notice, and have included with this form a libe used for this purpose).	list of companies se	nt offers of compensation (the Data Matrix form should			
SECTION I: METHOD OF DATA SUPP	ORT (Check one m	ethod only)			
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	✓ under the	completed list of data requirements (the Data Matrix form must be			
SECTION II: GENERAL (	OFFER TO PAY				
Required if using the cite-all method or when using the cite-all option under the select  I hereby offer and agree to pay compensation, to other persons, with regard to					
SECTION III: CERTI	FICATION				
I certify that this application for registration, this form for reregistration, or the application for registration, the form for reregistration, or the Data-Call-In response. In indicated in Section I, this application is supported by all data in the Agency's files that substantially similar product, or one or more of the ingredients in this product; and (2) i requirements in effect on the date of approval of this application if the application souguses.	addition, if the cite- (1) concern the pro s a type of data that	all option or cite-all option under the selective method is operties or effects of this product or an identical or twould be required to be submitted under the data			
I certify that for each exclusive use study cited in support of this registration the written permission of the original data submitter to cite that study.	or reregistration, the	at I am the original data submitter or that I have obtained			
I certify that for each study cited in support of this registration or reregistration submitter; (b) I have obtained the permission of the original data submitter to use the study is in the public literature; or (e) offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c) amount and terms of compensation, if any, to be paid for the use of the study.	study in support of the I have notified in wr	his application; (c) all periods of eligibility for iting the company that submitted the study and have			
I certify that in all instances where an offer of compensation is required, cop accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be evidence to the Agency upon request, I understand that the Agency may initiate action FIFRA.	e submitted to the	Agency upon request. Should I fail to produce such			
I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					
Signature Mancy Hueld	Date May 26, 2016	Typed or Printed Name and Title Nancy Huebl, Sr. Registration Specialist			

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

		DATA MATRIX			
Date 5/26/2016  Applicant's/Registrant's Name & Address  Wellmark International, 1501 E. Woodfield Rd., Suite 200W. Schaumburg, IL 60173		EPA Reg No./File Symbol 2724-446	Page 1 of 1		
		Product ZOECON RF-437 MOSQUITO GROWTH REGULATOR SR20.			
ngredient S-Methoprene					
Suideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.3300	Efficacy - Mosquitoes	TBD	Wellmark International	OWN	Submitted herewith
					-
					+
			-		
Signature Mancy	Duebl		Name and Title  Nancy Huebl, Sr. Registration Speci	alist	Date 05/26/2916



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

		DATA MATRIX			
Date 5/26/2016  Applicant's/Registrant's Name & Address  Wellmark International, 1501 E. Woodfield Rd., Suite 200W, Schaumburg, IL 60173		EPA Reg No./File Symbol 2724-446	Page 1 of 1		
		Product ZOECON RF-437 MOSQUITO GROWTH REGULATOR SR20			
ngredient S-Methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Wellmark International	OWN	
					4
			<del></del>		
					40.4
:::					
Signature 41 and	cy Huebl		Name and Title  Nancy Huebl, Sr. Registration Spec	ialist	Date 05/26/2916

# **21-Day Screen of Amendment** (Completed by Contractor)

21-day Expires on 6-21-16

**Document Part Of:** 2724 -446 **MRID, If Any:** 499355

Content Screen: Recommended to Pass/Fail

11-3 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Document returned to:

ANDREW BRYCE(AND

# PRIA 3 – 21 Day Content Screen Review Worksheet (EPA/OPP Use Only)

(EPA/OPP Use Only)

September 2012

Expe	erts In-Processing Signature:	7-16 Date	Fee I	Paid: Y	es <u>v</u>	<i>!</i>	
EPA	Reg. Number: 2724-446 EPA Receipt Date: 5-	31-1	6				
	Items for Review			Yes	No	N/A*	
1	Application Form (EPA Form 8570-1) signed & complete including package type						
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)					X	
2	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)						
3	Cartification with Payaget to Citation of Data (EBA Form 9570 24)						
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)				a Viene		
	If applicable, is there a letter of Authorization for exclusive use o	nly.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X	
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)						
5	C. L. div. Matte J (Fee address of the control of t	yes	no				
	a) Selective Method (Fee category experts use)  b) Cite-All (Fee category experts use)	X					
	c) Applicant owns all data (Fee category experts use)						
6	5 Copies of <u>Label</u> ( <u>Electronic labels on CD</u> are encouraged and guidance is available)						
7	Is the data package consistent with PR Notice 86-5						
8						X	

9	If applicable for conventional applications, reduced risk rationale	X
	Required Data and/or data waivers. See Footnote C.	
	a) List study (or studies) not included with application	
10		
Com	ments:  Documentation (for tail)  - All Required forms (conflicte	
	Mo liters to Review	
	PFN:1-03 (Pars) c. Fall PNF1D 479 355	
$\bigwedge$	16/7/16 Overall Hutur Parder Fee	

#### Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are strongly encouraged to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency even if a product is currently registered by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at <a href="inertsbranch@epa.gov">inertsbranch@epa.gov</a> and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the <a href="Chief of Microbial Pesticides Branch">Chief of Microbial Pesticides Branch</a>.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

#### Unapproved Inerts Identified on CSFs

#### All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

- Correct the application by, for instance, correcting the inert's identity or CAS
  number, providing documentation that the inert has been approved, or
  removing the unapproved inert from the CSF or replacing it with one that is
  approved for the application's uses; or
- 2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
- Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
- 4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

- Correct the application by, for instance, correcting the inert's identity or CAS
  number, providing documentation that the inert has been approved, or
  removing the unapproved inert from the CSF or replacing it with one that is
  approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

- Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
- Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

- B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.
- C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

June 6, 2016

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OPP Decision Number: D-518021

EPA File Symbol or Registration Number: 2724-446

Product Name: ZOECON RF-437 MOSQUITO GROWTH REGULATOR SR-20

EPA Receipt Date: 31-May-2016 EPA Company Number: 2724

Company Name: WELLMARK INTERNATIONAL

NANCY HUEBL WELLMARK INTERNATIONAL 1501 E. WOODFIELD ROAD, SUITE 200 WEST SCHAUMBURG, IL 60173

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B680

AMENDMENT;MICROBIAL/BIOCHEMICAL;REGISTERED SOURCE OF ACTIVE INGREDIENT;NO NEW USE(S);NO CHANGE TO AN ESTABLISHED TOLERANCE OR TOLERANCE EXEMPTION;REQUIRES DATA SUBMISSION;REDUCED FEE: ASSOCIATED WITH ANOTHER PRIA ACTION;

Please note that this amendment was coded as a secondary amendment with the amendment to Reg. No. 2724-392. There is an overpayment of \$1,592 which will be refunded when this action is completed. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-1259.

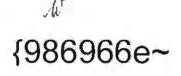
Sincerely,

my John

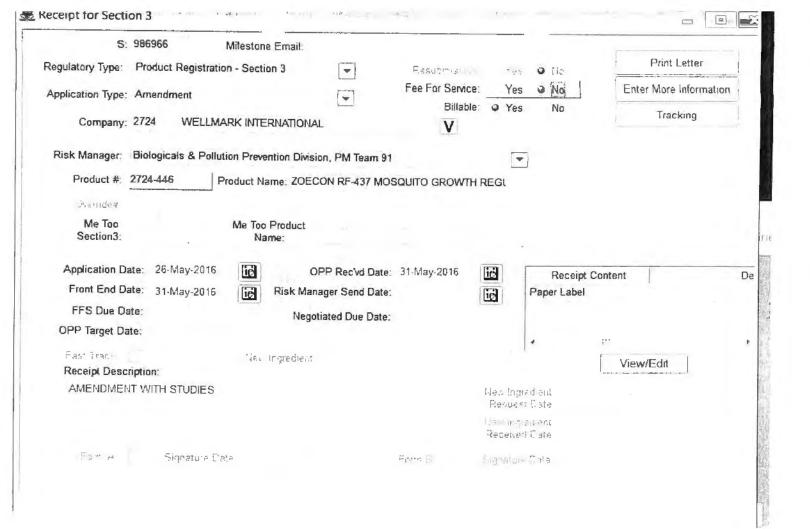
Front End Processing Staff

Information Technology & Resources Management Division

## Fee for Service



This package includes the following	for Division			
<ul><li>New Registration</li><li>Amendment</li></ul>	○ AD ◎ BPPD ○ RD			
<ul><li>Studies?</li><li>Fee Waiver?</li><li>volpay</li><li>Reduction:</li></ul>	Risk Mgr. 91			
Receipt No. S- EPA File Symbol/Reg. No. Pin-Punch Date:	986966 2724-446 5/31/2016			
This item is NOT subject t	o FFS action.			
Action Code:  Requested: [2340]  Granted: [3660, 1]  Amount Due: \$ \$297	Parent/Child Decisions:			
Inert Cleared for Intended Use  Reviewer: Andrew Byceland  Remarks:	Uncleared Inert in Product  Date: 6-2-/6			



#### **Nancy Huebl**

From:

notification@pay.gov

Sent:

Wednesday, May 25, 2016 2:40 PM

To:

Nancy Huebl

Subject:

Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

If you chose the option to receive payment reminders in your user profile and this is a deferred or recurring payment, you will receive a reminder email several days before the payment is processed. You may change your payment reminder preferences and email address in your user profile at any time.

If you wish to cancel this transaction, log in to your account at <a href="https://www.pay.gov/">https://www.pay.gov/</a> and choose the Pending tab of the Payment Activity page.

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 25RQPD10 Agency Tracking ID: 75022349433

Account Holder Name: Centrl Garden & Pet Company

Transaction Type: ACH Debit Transaction Amount: \$3,988.00 Payment Date: 05/26/2016

Account Type: Business Checking

Routing Number: 121000358

Account Number: \*\*\*\*\*\*\*\*\*0755

Transaction Date: 05/25/2016 03:39:49 PM EDT

Total Payments Scheduled: 1

Frequency: OneTime

Registration Number: 2724-446

Company Name: Wellmark International

Company Number: 2724 Action Code: R340

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



RE: Fast Track Amendments Reg. 2724-788

Cheryl Greene to: Nancy Huebl

Cc: Linda Hollis

12/13/2011 04:15 PM



Hi Nancy

Attached is our response letter accepting the changes proposed in the referenced application for EPA Reg. no. 2724-788. Please note that the acceptance is conditional on Wellmark making the changes and revisions I have noted on the label. if you have questions or need additional information, let me know.

1 attachment



[Untitled].pdf Wellmark 2724-788

Cheryl F. Greene
Office of Prevention, Pesticides and Toxic Substances
Office of Pesticide Programs, BPPD/BPB (7511P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20004

Tel: 703 308-0352 Fax 703 308-7026

Email: greene.cheryl@epa.gov

Nancy Huebl

Cheryl, I already received a stamped label for 27...

11/30/2011 03:37:40 PM

From:

Nancy Huebl <NHuebl@central.com> Cheryl Greene/DC/USEPA/US@EPA

To: Cheryl Greene/DC

Leonard Cole/DC/USEPA/US@EPA, Linda Hollis/DC/USEPA/US@EPA

Date:

11/30/2011 03:37 PM

Subject: RE: Fast Track Amendments

Cheryl, I already received a stamped label for 2724-446 dated October 6, 2011. I am however, still awaiting a label for 2724-788. Hope you are doing well. Nancy Huebl

----Original Message----

From: Greene.Cheryl@epamail.epa.gov [mailto:Greene.Cheryl@epamail.epa.gov]

Sent: Wednesday, November 30, 2011 2:14 PM

To: Nancy Huebl

Cc: Cole.Leonard@epamail.epa.gov; Hollis.Linda@epamail.epa.gov

Subject: RE: Fast Track Amendments

apologize and ask that you please notify the Sender by returning this e-mail and permanently deleting this communication from your computer, including destruction of any printed copies. Any views expressed herein are not necessarily those of the Company represented by this e-mail source. No contracts, agreements or legally binding understandings may be entered into solely by an e-mail communication

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## RE: Fast Track Amendments Cheryl Greene to: Nancy Huebl

12/02/2011 06:38 PM

#### Hi Nancy:

My records do not show that I sent you a stamped label and acceptance letter on October 6, 2011 for 2724-446. Would you please send me -- as soon as you possibly can - a copy of the label and letter that I forwarded to you? I am especially anxious to see the letter and label because it may be that someone else in the division may have sent the letter and label to you and inadvertently neglected to note that the action is closed. Before I send you the letter and label I alerted you to on November 30, I want to make sure that it will not be a duplicate. Sorry if this is confusing. Thanks.

Cheryl F. Greene

Office of Prevention, Pesticides and Toxic Substances
Office of Pesticide Programs, BPPD/BPB (7511P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20004

Tel: 703 308-0352 Fax 703 308-7026

Email: greene.cheryl@epa.gov

Nancy Huebi

Cheryl, I already received a stamped label for 27...

11/30/2011 03:37:40 PM

From: Nancy Huebl < NHuebl@central.com>
To: Cheryl Greene/DC/USEPA/US@EPA

Cc: Leonard Cole/DC/USEPA/US@EPA, Linda Hollis/DC/USEPA/US@EPA

Date: 11/30/2011 03:37 PM Subject: RE: Fast Track Amendments

Cheryl, I already received a stamped label for 2724-446 dated October 6, 2011. I am however, still awaiting a label for 2724-788. Hope you are doing well. Nancy Huebl

----Original Message-----

From: Greene.Cheryl@epamail.epa.gov [mailto:Greene.Cheryl@epamail.epa.gov]

Sent: Wednesday, November 30, 2011 2:14 PM

To: Nancy Huebl

Cc: Cole.Leonard@epamail.epa.gov; Hollis.Linda@epamail.epa.gov

Subject: RE: Fast Track Amendments

#### Hi Nancy:

I have completed the 2724-446 application. Its on Linda's desk for signature. I should get it back tomorrow and will forward an electronic copy of the label and acceptance letter to you as soon as get it. I'm working to complete 2724-788 (RF2047 DP) now. I expect to get it to Linda by cob tomorrow. I will keep you posted.

Cheryl F. Greene
Office of Prevention, Pesticides and Toxic Substances
Office of Pesticide Programs, BPPD/BPB (7511P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.

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Prevention Division (7511P) U.S. Environmental Protection Agency Ariel Rios Building 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460 Phone: 703.305.5412

Email: cole.leonard@epa.gov

---- Forwarded by Leonard Cole/DC/USEPA/US on 10/11/2011 04:01 PM -----

Linda Hollis/DC/USEPA/US

To: Steve Spaulding <SSpaulding@central.com>

Cc: Cheryl Greene/DC/USEPA/US@EPA, Leonard Cole/DC/USEPA/US@EPA

Date: 10/06/2011 04:17 PM

Subject: Re: Fast Track Amendments

See response in red below.

Linda A. Hollis, MS Chief, Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division Office of Pesticide Programs (7511P) U.S. Environmental Protection Agency One Potomac Yard 2777 S. Crystal Drive Arlington, VA 22202 hollis.linda@epa.gov (703) 308-8733 (phone) (703) 308-7026 (fax) Visit http://www.epa.gov/pesticides

"The journey of 1000 miles begins with one step.....Take the step"

Steve Spaulding <SSpaulding@central.com>

Linda Hollis/DC/USEPA/US@EPA To:

10/05/2011 03:49 PM Date:

Fast Track Amendments Subject:

Hi Linda -

We do not seem to be making progress on the Wellmark fast track amendments since the BPPD/BPIA meeting in July. The following is the status of 4 outstanding fast track amendments:

Zoecon RF-342EC - EPA Reg. No. 2724-788. Completed. 1. Email from L. Cole with letter and label coming today.

Submitted November 23, 2010.

Resolved conditions for approval with BPPD August

5, 2011

Received by email stamped approved label August 10, 2011

Still have not received the approval letter despite asking for it several times. We did not want to submit state registrations without making sure there were no changes to the label (verbally communicated from Cheryl Greene),

- therefore we missed the entire stored product pest season.

  2. RF2047 DP EPA Reg. No. 2724-788 Completed. Email from L. Cole with letter and label coming today.
  - Submitted November 23, 2010 at the same time as #1 since the amendment was basically the same for this product which is a dry version of #1. Interim efficacy study submitted has been reviewed and is questionable. Letter to be forwarded tomorrow.
  - Review has not been initiated. We missed the entire stored product pest season.
- 3. Altosid Liquid Larvacide (SR 20) EPA Reg. No. 2724-446. Add ULV application.Completed. Email from L. Cole with letter and label coming today.
  - Submitted 12/14/2010
  - Review not initiated. Missed entire mosquito season.
- 4. Altosid Liquid Larvacide (SR5) EPA Reg. No. 2724-392 Add ULV applicationCompleted. Email from L. Cole with letter and label coming today.
  - $\cdot$  Submitted 12/14/2010 at the same time as #3 and the amendment is the same as #3.
  - $\cdot$   $\;$  Review has not been initiated. We missed the entire mosquito season.

Taken alone, these amendments may not seem to mean much; however, taken together failure to get these amendments approved in a reasonable timely manner resulted in lost revenue for Wellmark this year. That is not what business needs in this economy.

One of the reasons I am pointing this situation out again, is that I am preparing another fast track alternate formulation amendment. This is a simple substitution of the preservative with

in Altosid Liquid Feed Supplement (EPA Reg. No. 2724-505). This is a time sensitive submission since we have to start manufacturing for the cattle horn fly season early next year. I understand that fast track amendments are lower than PRIA actions in priority and that resources are at a premium but it seems to me there has to be a way to improve processing fast track amendments. As you know, Maintenance Fees are supposed to cover these amendments. If there is any way that we can help alleviate this problem through Wellmark or BPIA, please let me know. In the meantime, I will make this fast track submission and hope that it can be reviewed in a timely manner. In addition, I hope that you are able to free up resources to complete the review of the fast track amendments that have been pending for almost a year. We will be discussing progress on Fast Track Amendments at the BPPD/BPIA meeting that is being scheduled for mid-October.

Please let me know if you have any questions or comments. Steve

\*\*\*\*\*\*\*\*\*\*

Steven R. Spaulding Senior Director, Regulatory Affairs Wellmark International / Farnam Companies, Inc. dba Central Life Sciences (847) 330.5380 ph (847) 330.5391 fx sspaulding@central.com

#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OCT 0 6 2011

OFFICE OF CHEMICAL SAFETY AND FOLL TOWNERS VENTION

Steven R. Spaulding
Senior Director, Regulatory Affairs
Wellmark International/Farnam Companies, Inc.
1100 East Woodfield Road, Suite 500
Schaumburg, IL 60173

Subject:

Label Amendment

Altosid® Liquid Larvicide SR20

EPA Reg. No.: 2724-446

Your submission dated December 14, 2010

Decision Number: 443311

Dear Mr. Spaulding:

The amendment referred to above submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(5), is acceptable provided that you:

- Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2) Submit two (2) copies of your final printed labeling before you release the product for shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags or drum labels.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Should you have any questions, you may contact Ms. Cheryl Greene directly at (703) 308-0352 or via email at greene.cheryl@epa.gov.

Sincerely,

Linda A. Hollis

Linda A. Hollis, Chief Biochemical Pesticides Branch Biopesticides and Pollution (7511P) [] optional wording

#### **ZOECON RF-437 MOSQUITO GROWTH REGULATOR SR-20**

Alternate brand names: Zoëcon® Altosid® Liquid Larvicide Concentrate

Strike Professional Midge Control

Prevents emergence of adult floodwater mosquitoes

[Prevents the emergence of adult filter [moth] flies, and midges]

[Keeps infestations under control]

Prevents emergence of adult fleas up to 8 weeks outdoors

Controls pre-adult fleas (larvae) up to 8 weeks

Biorational [approach to] flea control outdoors

Microencapsulated Formula

Prevents adult mosquito emergence (including those which may transmit West Nile Virus)

For control of mosquito larvae using ULV application

#### **ACTIVE INGREDIENT:**

(S)-Methoprene (CAS #65733-16-6)	20%
OTHER INGREDIENTS:	80%
TOTAL	100%

Formulation contains 1.72 lb/gal (205.2 g/l) active ingredient

### KEEP OUT OF REACH OF CHILDREN CAUTION

See Back Panel For Additional Precautionary Statements

BECAUSE OF THE UNIQUE MODE OF ACTION OF ZOECON RF-437 MOSQUITO GROWTH REGULATOR SR-20, SUCCESSFUL USE REQUIRES FAMILIARITY WITH SPECIAL TECHNIQUES FOR APPLICATION TIMING AND TREATMENT EVALUATION. SEE GUIDE TO PRODUCT APPLICATION OR CONSULT LOCAL MOSQUITO ABATEMENT AGENCY.

EPA Reg. No. 2724-446 EPA Est. No.

**NET CONTENTS:** 

**ACCEPTED** 

OCT 0 6 2011.

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. Nu 2724-446

#### PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

Call a poison co	ontrol center or doctor immediately for treatment advice.
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
If on skin or clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> </ul>
Have the produ	ct container or label with you when calling a poison control center or doctor, or nent. You may also contact 1-800-[phone number] for emergency medical

[Note: First Aid statement paragraph format may be used if space is limited.]

#### **ENVIRONMENTAL HAZARDS**

Do not contaminate water when disposing of rinsate or equipment washwaters.

#### [INTRODUCTION]

[Zoecon RF-437 is a unique product that controls [mosquitoes][filter [moth] flies (*Psychoda* spp.)][midges (*Chironomidae*)] and other nuisance aquatic insect species [infesting waste water treatment facilities]. Zoecon RF-437 contains an insect growth regulator (IGR) that is effective on the developing [immature] stages of insect pests. Zoecon RF-437 does not kill adults but affects the larval stages as they grow and develop. Zoecon RF-437 stops the formation of pupa of insect pests, thereby eliminating adult populations. Zoecon RF-437 stops the cycle of reproduction, keeping pest infestations under control. Continued use of the product prevents these pests from rebounding into unmanageable infestations.]

#### DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

#### MIXING AND HANDLING INSTRUCTIONS:

- SHAKE WELL BEFORE USING. Zoecon RF-437 may separate on standing and must be thoroughly agitated prior to dilution.
- Do not mix with oil; use clean equipment.
- 3. Partially fill spray tank [container] with water; then add the labeled amount of Zoecon RF-437, agitate and complete filling. Mild agitation during application is desirable. [Accomplish agitation by use of recirculation pump, mixer, air pump, or other suitable equipment.]
- 4. Use spray solution within 48 hours; always agitate before spraying.

#### **APPLICATIONS**

**Mosquito Control:** Zoecon RF-437 must be applied to 2nd, 3rd, or 4th larval instars of floodwater mosquitoes to prevent adult emergence. Treated larvae continue normal development to the pupal stage where they die. This insect growth regulator has no effect when applied to pupae or adult mosquitoes. Zoecon RF-437 has sufficient field life to be effective at label rates when applied to larval stages under varying field conditions. For further information, see **Guide to Product Application**.

#### For Control of Mosquito Larvae Using ULV Application:

For ground application to terrestrial sites, apply at the rate of ¾ - 1 ounce of product per acre to water-holding containers and other small bodies of water that breed mosquitoes. Use equipment capable of applying a fine mist or ULV. Follow equipment manufacturer's recommendations when making applications. Direct spray applications to sites where mosquitoes breed. These sites include tires and tire piles, potted plants, tree holes, garbage bins, cans, birdbaths, rain barrels, and other water-holding containers and small bodies of water.

[Waste Water Treatment Facility Pests: Use Zoecon RF-437 in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where midges, filter [moth] flies, and other nuisance aquatic insect pests are a problem.]

### [What to Expect in Waste Water Treatment Facilities] [Continuous Flow Sewage {waste water}

In order to achieve effective results, Zoecon RF-437 must be applied on a daily basis for at least 2 weeks. Failure to apply the material on a daily basis during the treatment phase may result in erratic results. Following initial applications of Zoecon RF-437, a gradual reduction in the number of adult pests will be seen over approximately a 1 week period. Reduction in adult populations will be very noticeable within a two week period following continuous application. Due to varying conditions or heavy infestations, the period to expect control may be longer. Since the mode of action of Zoecon RF-437 is to prevent adult emergence, existing adults and pupa present at the time of initial application will complete their life cycle.

As adult suppression peaks, use a maintenance rate of Zoecon RF-437 for continuous protection from population rebound. However, if application of Zoecon RF-437 is halted following population suppression, rebound of the population can be expected within 2 to 3 weeks after stopping application. For continuous suppression throughout the pest season, continue application of Zoecon RF-437.

#### Sludge or Solid Waste Applications

For solid waste applications, use 5 ounces per million gallons of sludge or solids. Apply the dilution until the drying beds have been filled. Following filling of the drying beds, the application of the dilution may be halted. Make applications of the dilution at the <u>influent</u> side as the sludge or solids enter into the drying beds. Application of Zoecon RF-437 to solids will prevent the emergence of adult insect pests thereby keeping infestations under control.]

#### METHODS OF APPLICATION

**Aerial:** Use the amount of Zoecon RF-437 listed below in sufficient water to give complete coverage. One-half to 5 gallons of spray solution per acre (4.7 to 46.8 liters/hectare) is usually satisfactory. Do not apply when weather conditions favor drift from areas treated.

**Ground:** Determine the average spray volume used per acre by individual operators and/or specific equipment. Mix Zoecon RF-437 in the appropriate volume of water to give the rate per acre shown below.

[Waste Water Treatment Facilities:] [Dilute Zoecon RF-437 with water prior to use. Apply Zoecon RF-437 with a metering pump, drip bucket or other suitable equipment. Metering pumps are the most efficient and accurate method of application. Appropriate dilution of product will be influenced by the method of application. Depending on the dosage rate, prepare the desired volume of dilution to apply over a {6 – 8 hour period} {24 hour period (day tank)}, or in cases of sludge beds, applied until the beds have been filled. When using delivery devices, it is important to calibrate the device to deliver the required amount of Zoecon RF-437 over a {6 – 8 hour period} {24 hour period}. {Sufficient material may be mixed in advance to provide for applications longer than 24 hours.}][For best results, use metering pumps that are capable of deliverying material for greater than 24 hours.]

#### APPLICATION RATE

Mosquitoes: Apply 3/4 to 1 fl oz of Zoecon RF-437 per acre (55 to 73 ml/hectare) in water as directed.

#### For Control of Mosquito Larvae Using ULV Application:

Apply at ¾ - 1 ounce per acre. Reapply as breeding sites become reinfested or when monitoring indicates an increase in adult populations.

#### [Waste Water Treatment Pests:]

[Initial Application - 4 - 5 ounces Zoecon RF-437 per 1 million gallons of sewage [waste water] in sufficient water to uniformly apply at the influent side over a 24 hour period.]

[Maintenance Rate - 2.5 - 3.0 ounces Zoecon RF-437 per 1 million gallons of sewage [waste water] in sufficient water to uniformly apply at the influent side over a 24 hour period.]

[To achieve effective results, make initial application rates on a daily basis for 2 weeks without interruption. Use sufficient water/Zoecon RF-437 to achieve uniform application to sewage [waste water] over a 24 hour period. Apply the dilution at the <u>influent</u> side of the particular area to be treated.]

[Maintain initial rate of application for two weeks and then follow the directions for the maintenance rate for continued effectiveness.]

#### [Application to Waste Water - Trickling Filter:

Apply 5 ounces Zoecon RF-437 per 1 million gallons of sewage [waste water] in sufficient water to uniformly apply the material. Apply at times of low periods of flow (typically evening through early morning hours) for 6 – 8 hours. Discontinue treatment during peak flow periods and repeat applications the following day during the low flow period. Continue this application method for 7 to 10 days or until suppression of pests is achieved. Repeat applications every 15 days or as necessary to control pests.]

Fleas: Apply 1 fluid ounce of Zoecon RF-437 per 1000 square feet in water as directed.

#### APPLICATION SITES

Pastures: Zoecon RF-437 may be applied after each flooding without removal of grazing livestock.

Rice: Zoecon RF-437 must be applied to 2nd, 3rd, and/or 4th instar larvae of mosquitoes found in rice, usually within 4 days after flooding. Zoecon RF-437 treatment may be repeated with each flooding.

Intermittently Flooded Noncrop Areas: Apply Zoecon RF-437 as directed above when flooding may result in floodwater mosquito hatch. Typical sites include freshwater swamps and marshes, salt marshes, woodland pools and meadows, dredging spoil sites, drainage areas, waste treatment and settling ponds, ditches and other natural and manmade depressions.

**Crop Areas:** Apply Zoecon RF-437 to irrigated croplands after flooding to control mosquito emergence. Examples of such sites are vineyards, rice fields (including wild rice), date palm orchards, fruit and nut orchards and berry fields and bogs. Irrigated pastures may be treated after each flooding without removal of livestock.

**Dense vegetation or canopy areas:** Apply a Zoecon RF-437 sand mixture using standard granular dispersal equipment. For detailed preparation instructions, refer to Guide to Product Application.

For Fleas Outdoors: (1) When using a hose-end sprayer, place 0.75 ounces of Zoecon RF-437 in bottle, add 6 ounces of water and apply at low pressure. (2) Make sure to apply at 0.75 ounces of Zoecon RF-437 per 15 gallons of water. (3) Apply 0.75 ounces of Zoecon RF-437 in 15 gallons of water to every 750 square feet of residential turf. (4) Pay particular attention to areas where pets frequent, such as, in and around dog houses and runs, and around shrubs, outside decks, and porches. (5) If a large population of fleas is present, use [an outdoor flea control product][brand name of outdoor flea control product] for initial kill of adult fleas.

[Waste Water Treatment Facilities: Apply Zoecon RF-437 to sewage as it flows into trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water facilities where pests are a problem.

Apply Zoecon RF-437 as the sewage enters {influent areas} the targeted processing area. Failure to add the material at the influent side may result in erratic results.]

TANK MIXING INSTRUCTIONS: Zoecon RF-437 may be tank mixed with liquid *Bacillus* thuringiensis variety israeliensis (B.t.i.) formulations. The ratio of B.t.i. to Zoecon RF-437 is to range from 24:1 to 50:1 (volume/volume). For example, to prepare a 50:1 tank mix, add 1 gallon of RF-437 to 50 gallons of B.t.i. This tank mix can be applied to sites listed above at rates of 2 to 16 fluid ounces/acre (0.15-1.2 liters/hectare).

The user, at his discretion can [tank] mix Zoecon RF-437 with an adulticide currently registered for use unless the product label prohibits such mixing. Use of the resulting tank mixture must be used in accordance with the more restrictive label limitations and precautions.

**CHEMIGATION:** Refer to supplemental labeling entitled "Guide to Product Application" for use directions for chemigation. Do not apply this product through any irrigation system unless the supplemental labeling on chemigation is followed.

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Storage: Store in a cool place, away from other pesticides, food and feed. In case of leakage or spill, soak up with sand or another absorbent material. Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal: Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptyng. Triple rinse as follows. Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

For information, call 1/800-XXX-XXXX or visit our Web site: [URL].

Wellmark International 1501 East Woodfield Road 200W Schaumburg, IL 60173

Made in USA

# ZOECON RF-437 MOSQUITO GROWTH REGULATOR SR-20 PREVENTS EMERGENCE OF ADULT FLOODWATER MOSQUITOES

#### **GUIDE TO PRODUCT APPLICATION**

#### FOR THE FIRST TIME USER

ZOECON RF-437 MOSQUITO GROWTH REGULATOR SR-20 (SR-20) is the result of extensive research into the intricacies of natural biochemical and physiological development of insects. New chemical technology and biological findings were combined to develop a unique mosquito larvicide.

SR-20, an insect growth regulator (IGR), acts by inducing morphological changes which interfere with normal development. These effects, not immediately apparent, result in the failure of adult mosquitoes to emerge from pupae. SR-20 is <u>not</u> a conventional pesticide. It does not produce the nondiscriminatory rapid, directly toxic effects that are associated with traditional larvicides. SR-20 differs from other larvicides you may have used only in the manner and time course of its action <u>after</u> application.

SR-20 is applied to second, third or fourth instar larvae using standard larviciding equipment in a manner similar to other larvicides. After application to second, third or fourth instar larvae at recommended rates, absolutely no effects on larvae will be observed. They will continue developing normally and will pupate. Pupae will appear unaffected, but will eventually die. Adults will not emerge. Infrequently, a few adults may be seen at the water surface but they will have abnormalities preventing flight and will not survive. Because the effect of SR-20 is neither larval death nor widespread mortality immediately following pupation, the number of adults which emerge is the only criterion for accurately assessing control. Checks by dip counts during larval and pupal stages will give no measure of effectiveness.

Refer to the following diagram and checklist, in addition to label instructions for guidance in timing of application and performance evaluation. They will assist you in obtaining the best possible results with this unique product.

Wellmark International 1501 East Woodfield Road 200W Schaumburg, IL 60173

For information, call 1/800-XXX-XXXX

The information presented herein, while not guaranteed, is to the best of our knowledge true and accurate. No warranty or guarantee, express or implied, is made regarding the performance or stability of any product, since the manner of use and conditions of storage and handling are beyond our control.

#### **CHECK LIST**

Things to remember when using SR-20

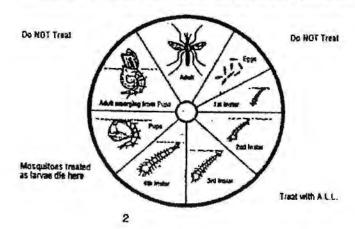
#### DO the following:

- DO treat second, third and/or fourth instar larvae, not pupae or adults. (First instar larvae are so small they are not readily detectable.)
- DO wait until treated larvae have pupated. Then <u>collect pupae</u> and transfer to laboratory to observe for emergence of adults.
- DO observe pupae for several days, since death of IGR treated mosquitoes occurs when pupae would normally emerge as adults. (Careful observation is necessary since dead pupae decompose rapidly and thus are not easily seen.)
- 4. DO monitor emerging adults at the treatment site. This absolutely requires that emergence traps be placed in treatment areas to capture adult mosquitoes as they emerge.

#### DO NOT do the following:

- DO NOT take dip counts of larvae after treatment for the purpose of performance evaluation.
   Normal looking larvae will be present.
- DO NOT take dip counts of pupae after treatment for the purpose of performance evaluation.Normal looking pupae will be seen but these will not develop into normal adults.
- 3. DO NOT think SR-20 has failed if some adult mosquitoes are flying in treated areas; they probably have flown in from nearby untreated areas. Numbers 2 and 4 of the "DO" checklist are the only methods of accurately assessing effectiveness.
- 4. DO NOT spray again, either with SR-20 or a conventional insecticide, because larvae or pupae are present after application. This is normal. The effectiveness of SR-20 can only be measured by lack of adult emergence.

### LIFE CYCLE OF MOSQUITO WHEN TO APPLY ZOECON SR-20 MOSQUITO GROWTH REGULATOR



#### Preparation of ALTOSAND® Granular Formulation

#### An "On-Site" Method of Preparing a Granular Formulation of SR-20

#### INTRODUCTION

A method of application of SR-20, using sand as a carrier, has been developed for use in floodwater mosquito breeding areas with dense vegetation or canopy. The characteristics of ALTOSAND provide excellent foliage penetration, insuring that the active ingredient reaches the water where it is released from the sand.

ALTOSAND will prevent the emergence of species of the floodwater mosquito complex when applied to second, third or fourth larval instars at a rate of ten to thirteen pounds per acre.

#### **PREPARATION INSTRUCTIONS**

The following materials are required to prepare a 100 lb. batch of ALTOSAND:

99 lb washed, dry sand (20-45 mesh) 0.5 lb SR-20 (15 fluid oz/lb) 0.5 lb HiSil 233 (silicon dioxide) Small Funnel Cement Mixer

- 1. Measure the time required for a level funnel full of sand to empty.
- Into a rotating-type mixer, place 99 lb of dry (20-45 mesh) sand. While the mixer is rotating, slowly pour 0.5 lb (7.5 fl oz) of SR-20 onto the sand. (If better wetting is required, SR-20 may be diluted in up to an equal volume of water.)
- Mix until the sand is uniformly coated with SR-20 (usually 5 to 10 minutes).
- 4. Stop the mixer and add 0.5 lb of HiSil 233. Cover the mixer to reduce dust. Start the mixer and run for approximately 5 minutes. (The quantity of HiSil 233 necessary to achieve a dry, free-flowing mixture will vary depending on the particle size distribution and moisture of the sand.)
- 5. Compare the flow rate of the ALTOSAND mixture with that of untreated sand in Step No. 1. Add more HiSil if it flows significantly slower and reduce the amount of HiSil in subsequent batches if the mixture flows at the same or a faster rate and is excessively dusty.

#### APPLICATION RATE AND METHODS

Apply at a rate of 10 to 13 lb of the final mixture per acre, using standard granular dispersal equipment.

Chemigation: Apply this product only through flood (basin), furrow or border irrigation systems. Do not apply this product through any other type of irrigation system. Crop injury, lack of effectiveness or illegal pesticide residues in the crop can result from nonuniform distribution of treated water. If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Flood (Basin), Furrow and Border Chemigation: Systems using a gravity flow pesticide dispensing system must meter the pesticide into the water at the head of the field and downstream of a hydraulic discontinuity such as a drop stucture or weir box to decrease potential for water source contamination from backflow if water flow stops.

Systems utilizing a pressurized water and pesticide injection system must meet the following requiremments:

- \* The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
- \* The pesticide injection pipeline must contain a functional, automatic quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- \* The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- \* The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- \* The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where the pesticide distribution is adversely affected.
- \* Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

A pesticide supply tank is recommended for the application of SR-20 by chemigation.

ALTOSAND is a registered trademark of Wellmark International.

EPA Reg. No.: 2724-446

### **ZOËCON® ALTOSID® LIQUID LARVICIDE CONCENTRATE**

Supplemental Labeling				
			 	 _

#### FOR CONTROL OF MOSQUITO LARVAE USING ULV APPLICATION

EPA Reg. No. 2724-446

#### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Read the label affixed to the container for **Zoëcon® Altosid® Liquid Larvicide Concentrate** before using.

#### Important

Use of Zoëcon® Altosid® Liquid Larvicide Concentrate according to this labeling is subject to the use precautions and limitations imposed by the label affixed to the container for Zoëcon® Altosid® Liquid Larvicide Concentrate.

#### For Control of Mosquito Larvae Using ULV Application:

For ground application to terrestrial sites, apply at the rate of % - 1 ounce of product per acre to water-holding containers and other small bodies of water that breed mosquitoes. Use equipment capable of applying a fine mist or ULV. Follow equipment manufacturer's recommendations when making applications. Direct spray applications to sites where mosquitoes breed. These sites include tires and tire piles, potted plants, tree holes, garbage bins, cans, birdbaths, rain barrels, and other water-holding containers and small bodies of water. Reapply as breeding sites become reinfested or when monitoring indicates an increase in adult populations.

For information or in case of emergency, contact 1-800-248-7763.

This labeling must be in the possession of the user at the time of application.

Altosid and Zoëcon are registered trademarks of Weilmark International.

#### Registrant:

Wellmark International

1501 East Woodfield Road 200W Schaumburg, Illinois 60173 www.altosid.com

This supplemental label expires on	and must not be used or distributed
after this date.	
Made in the USA	



Re: Can you tell me what data are required to determine if an IGR can be acceptably applied at ultra low volume for the control of mosquitos? MORE Angela Gonzales to: Cheryl Greene 12/01/2011 12:32 PM

Cc: Clara Fuentes, Linda Hollis, Russell Jones

Hi Cheryl,

Just to add to Russ' comment...

What are the current uses for the product? Depending on how the product is currently used, there may need to be some data requirements addressed if the addition of ULV uses will change anything (e.g.: tox rationale, physical/chemical props, etc.).

Angela L. Gonzales
Environmental Protection Specialist
U.S. Environmental Protection Agency
Biopesticides & Pollution Prevention Division (7511P)
1200 Pennsylvania Ave, NW
Washington, DC 20460
gonzales.angela@epa.gov
703-308-0460

Cheryl Greene

Guys: I'm working on a label amendment from...

11/29/2011 08:09:51 PM

From: Cheryl Greene/DC/USEPA/US

To: Angela Gonzales/DC/USEPA/US@EPA, Clara Fuentes/DC/USEPA/US@EPA
Cc: Linda Hollis/DC/USEPA/US@EPA, Russell Jones/DC/USEPA/US@EPA

Date: 11/29/2011 08:09 PM

Subject: Can you tell me what data are required to determine if an IGR can be acceptably applied at ultra

low volume for the control of mosquitos? MORE

#### Guys:

I'm working on a label amendment from Wellmark to among other things add ultra low volume (ULV) applications to an existing label. I've checked the submitted data for the product in question and did not readily find any studies to support this application method. I also check the data requirements table and found nothing. I can continue working to figure but before doing so, I thought I would check with you guys in the off chance that one of you know the answer off of the top .... If you know what is required, please let me know. Alternately, if you can point me to where I should look to find this answer, again I would appreciate. Thanks in advance for you help.

#### Regards,

i'M WORKING ON A LABEL AMENDMENT Cheryl F. Greene Office of Prevention, Pesticides and Toxic Substances Office of Pesticide Programs, BPPD/BPB (7511P) U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, N.W. Washington, DC 20004

Tel: 703 308-0352 Fax 703 308-7026 Email: greene.cheryl@epa.gov



Re: Can you tell me what data are required to determine if an IGR can be acceptably applied at ultra low volume for the control of mosquitos? MORE 🗋 Russell Jones to: Cheryl Greene 11/30/2011 07:22 AM

Cc: Angela Gonzales, Clara Fuentes, Linda Hollis

History:

This message has been replied to.

The short answer is: Efficacy studies using the new method at the max app rate for the new method.

Russell S. Jones, Ph.D., Senior Biologist **OPP Invasive Species Contact** Chair, Biochemical Classification Committee Biochemicals Branch Science Review Process Leader Biopesticides & Pollution Prevention Division Office of Pesticide Programs

Ph: 703/308-5071 FAX: 703/308-7026 jones.russell@epa.gov http://www.epa.gov/pesticides/biopesticides

Mailing Address: U. S. Environmental Protection Agency (7511P) 1200 Pennsylvania Avenue NW Washington, DC 20460-0001

Office Address: 2777 South Crystal Drive One Potomac Yard, 8th Floor Arlington, VA 22202

"What can be asserted without evidence, can also be dismissed without evidence" - Christopher Hitchens

Cheryl Greene

Guys: I'm working on a label amendment from...

11/29/2011 08:09:51 PM

Cheryl Greene/DC/USEPA/US

From: To: Angela Gonzales/DC/USEPA/US@EPA, Clara Fuentes/DC/USEPA/US@EPA

Cc: Linda Hollis/DC/USEPA/US@EPA, Russell Jones/DC/USEPA/US@EPA

Date: 11/29/2011 08:09 PM

Subject: Can you tell me what data are required to determine if an IGR can be acceptably applied at ultra

low volume for the control of mosquitos? MORE

#### Guys:

I'm working on a label amendment from Wellmark to among other things add ultra low volume (UEV) applications to an existing label. I've checked the submitted data for the product in question and did not readily find any studies to support this application method. I also check the data requirements table and found nothing. I can continue working to figure but before doing so, I thought I would check with you guys in the off chance that one of you know the answer off of the top .... If you know what is required, please let me know. Alternately, if you can point me to where I should look to find this answer, again I would appreciate. Thanks in advance for you help.

#### Regards,

I'M WORKING ON A LABEL AMENDMENT Cheryl F. Greene Office of Prevention, Pesticides and Toxic Substances Office of Pesticide Programs, BPPD/BPB (7511P) U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, N.W.

Washington, DC 20004

Tel: 703 308-0352 Fax 703 308-7026

Email: greene.cheryl@epa.gov

Washington, DC 20004

Tel: 703 308-0352 Fax 703 308-7026

Email: greene.cheryl@epa.gov

From: Nancy Huebl <NHuebl@central.com>
To: Leonard Cole/DC/USEPA/US@EPA

Cc: Cheryl Greene/DC/USEPA/US@EPA, Steve Spaulding

<SSpaulding@central.com>, Mark Taylor <MTaylor@central.com>

Date: 11/15/2011 02:26 PM

Subject: RE: Fast Track Amendments

Leonard, please see below. We still have not received anything back on the 2724-788 RF2047 DP (dust) amendment that is pending since Dec 2010. Please advise status. Thanks.

2724-788: RF2047 DP (dust formulation) label amendment. We have not received anything on this action yet. We are looking for a stamped label. There was a Linda Hollis email response to Steve that an interim efficacy study we submitted was reviewed and is questionable and that a letter would be forwarded to us on that, not yet received.

Nancy Huebl 847-330-5376

----Original Message----

From: Cole.Leonard@epamail.epa.gov [mailto:Cole.Leonard@epamail.epa.gov]

Sent: Thursday, October 13, 2011 2:09 PM

To: Nancy Huebl

Cc: Steve Spaulding; Greene.Cheryl@epamail.epa.gov

Subject: RE: Fast Track Amendments

Hi Nancy,

I will have all of the corrected information to you by COB tomorrow. I simply need to confirm one item with our efficacy reviewer. Thanks for your patience.

Leonard S. Cole, Jr., Senior Regulatory Specialist Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division (7511P)
U.S. Environmental Protection Agency Ariel Rios Building 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460 Phone: 703.305.5412

Email: cole.leonard@epa.gov

From: Nancy Huebl <NHuebl@central.com>
To: Leonard Cole/DC/USEPA/US@EPA

Cc: Steve Spaulding <SSpaulding@central.com>

Date: 10/11/2011 04:42 PM

Subject: RE: Fast Track Amendments

Leonard, thanks so much for your call on our pending actions. Sorry for the confusion and here is what is outstanding:

2724-427 RF9811 EC (was Zoecon RF342 EC) - liquid formulation We received an EPA stamped approved label dated August 10, 2011. The stamped label did not include a cover letter. When I spoke to Cheryl Greene in August she advised me that the letter would state the parameters/timelines for the data we agreed to submit. That is the letter that we are requesting.

2724-788-RF2047 DP (dust formulation) label amendment. We have not received anything on this action yet. We are looking for a stamped label. There was a Linda Hollis email response to Steve that an interim efficacy study we submitted was reviewed and is questionable and that a letter would be forwarded to us on that, not yet received.

Hopefully, this is clearer, if you have any questions, give me a call and we'll try again. Thanks very much for your help on resolving these outstanding actions. Nancy Huebl 847-330-5376

----Original Message----

From: Cole.Leonard@epamail.epa.gov [mailto:Cole.Leonard@epamail.epa.gov]

Sent: Tuesday, October 11, 2011 3:02 PM

To: Nancy Huebl

Subject: Fw: Fast Track Amendments

As promised, please see attached.

Leonard S. Cole, Jr., Senior Regulatory Specialist Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division (7511P) U.S. Environmental Protection Agency Ariel Rios Building 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460

Phone: 703.305.5412

Email: cole.leonard@epa.gov

---- Forwarded by Leonard Cole/DC/USEPA/US on 10/11/2011 04:01 PM -----

From: Linda Hollis/DC/USEPA/US

To: Steve Spaulding <SSpaulding@central.com>

Cc: Cheryl Greene/DC/USEPA/US@EPA, Leonard Cole/DC/USEPA/US@EPA

Date: 10/06/2011 04:17 PM

Subject: Re: Fast Track Amendments

See response in red below.

Linda A. Hollis, MS
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)
Visit http://www.epa.gov/pesticides

"The journey of 1000 miles begins with one step.....Take the step"

From: Steve Spaulding <SSpaulding@central.com>

To: Linda Hollis/DC/USEPA/US@EPA

Date: 10/05/2011 03:49 PM

Subject: Fast Track Amendments

#### Hi Linda -

We do not seem to be making progress on the Wellmark fast track amendments since the BPPD/BPIA meeting in July. The following is the status of 4 outstanding fast track amendments:

1. Zoecon RF-342EC - EPA Reg. No. 2724-788. Completed.

Email from L. Cole with letter and label coming today.

Submitted November 23, 2010.

Resolved conditions for approval with BPPD August
 5, 2011

Received by email stamped approved label August 10,

Still have not received the approval letter despite asking for it several times. We did not want to submit state registrations without making sure there were no changes to the label (verbally communicated from Cheryl Greene), therefore we missed the entire stored product pest season.

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L. Cole with letter and label coming today.

Submitted November 23, 2010 at the same time as #1 since the amendment was basically the same for this product which is a dry version of #1. - Interim efficacy study submitted has been reviewed and is questionable. Letter to be forwarded tomorrow.

Review has not been initiated. We missed the entire

stored product pest season.

3. Altosid Liquid Larvacide (SR 20) - EPA Reg. No. 2724-446. Add ULV application.Completed. Email from L. Cole with letter and label coming today.

Submitted 12/14/2010

- Review not initiated. Missed entire mosquito season.
- 4. Altosid Liquid Larvacide (SR5) EPA Reg. No. 2724-392 Add ULV applicationCompleted. Email from L. Cole with letter and label coming today.

Submitted 12/14/2010 at the same time as #3 and the

Taken alone, these amendments may not seem to mean much; however, taken together failure to get these amendments approved in a reasonable timely manner resulted in lost revenue for Wellmark this year. That is not what business needs in this economy.

One of the reasons I am pointing this situation out again, is that I am preparing another fast track alternate formulation amendment. This is a simple substitution of the preservative with

in Altosid Liquid Feed Supplement (EPA Reg. No. 2724-505). This is a time sensitive submission since we have to start manufacturing for the cattle horn fly season early next year. I understand that fast track amendments are lower than PRIA actions in priority and that resources are at a premium but it seems to me there has to be a way to improve processing fast track amendments. As you know, Maintenance Fees are supposed to cover these amendments. If there is any way that we can help alleviate this problem through Wellmark or BPIA, please let me know. In the meantime, I will make this fast track submission and hope that it can be reviewed in a timely manner. In addition, I hope that you are able to free up resources to complete the review of the fast track amendments that have been pending for almost a year. We will be discussing progress on Fast Track Amendments at the BPPD/BPIA meeting that is being scheduled for mid-October.

Please let me know if you have any questions or comments. Steve

\*\*\*\*\*\*\*\*\*

Steven R. Spaulding Senior Director, Regulatory Affairs Wellmark International / Farnam Companies, Inc. dba Central Life Sciences (847) 330.5380 ph (847) 330.5391 fx sspaulding@central.com

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#### Hi Nancy:

I have completed the 2724-446 application. Its on Linda's desk for signature. I should get it back tomorrow and will forward an electronic copy of the label and acceptance letter to you as soon as get it. I'm working to complete 2724-788 (RF2047 DP) now. I expect to get it to Linda by cob tomorrow. I will keep you posted.

Cheryl F. Greene
Office of Prevention, Pesticides and Toxic Substances
Office of Pesticide Programs, BPPD/BPB (7511P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20004

Tel: 703 308-0352 Fax 703 308-7026

Email: greene.cheryl@epa.gov

From: Nancy Huebl <NHuebl@central.com>
To: Leonard Cole/DC/USEPA/US@EPA

Cc: Cheryl Greene/DC/USEPA/US@EPA, Steve Spaulding

<SSpaulding@central.com>, Mark Taylor <MTaylor@central.com>

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U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
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U.S. Environmental Protection Agency Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
Phone: 703.305.5412

cole.leonard@epa.gov Email:

---- Forwarded by Leonard Cole/DC/USEPA/US on 10/11/2011 04:01 PM -----

Linda Hollis/DC/USEPA/US

Steve Spaulding <SSpaulding@central.com>

Cheryl Greene/DC/USEPA/US@EPA, Leonard Cole/DC/USEPA/US@EPA

Date: 10/06/2011 04:17 PM

Subject: Re: Fast Track Amendments

See response in red below.

Linda A. Hollis, MS Chief, Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division Office of Pesticide Programs (7511P) U.S. Environmental Protection Agency One Potomac Yard 2777 S. Crystal Drive Arlington, VA 22202 hollis.linda@epa.gov (703) 308-8733 (phone) (703) 308-7026 (fax) Visit http://www.epa.gov/pesticides

"The journey of 1000 miles begins with one step.....Take the step"

Steve Spaulding <SSpaulding@central.com>

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  - Submitted 12/14/2010 at the same time as #3 and the amendment is the same as #3.
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Please let me know if you have any questions or comments. Steve

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Steven R. Spaulding Senior Director, Regulatory Affairs Wellmark International / Farnam Companies, Inc. dba Central Life Sciences (847) 330.5380 ph (847) 330.5391 fx sspaulding@central.com

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WASHINGTON, D.C. 20460

#### DEC 01 20H

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Steven R. Spaulding
Senior Director, Regulatory Affairs
Wellmark International/Farnam Companies, Inc.
1100 East Woodfield Road, Suite 500
Schaumburg, IL 60173

Subject:

Label Amendments for Altosid Liquid Larvicide

EPA Reg. No. 2724-446

Your submissions dated: December 14, 2010 adding ULV instructions, revising ingredient and precautionary statements (EPA Decision #443311) and December 16, 2010 – Adding Supplemental labeling (EPA Decision #

444119)

Dear Mr. Spaulding:

The applications to amendment the label for the above referenced product, submitted in connection with the Federal Insecticide Fungicide and Rodenticide Act, section 3(c)(7)(A) as amended, have been received.

- 1. The December 14, 2010, amendment seeks to add ultra low volume application directions, and revise the ingredient, precautionary and warranty statements on the label. The Agency has determined that the amendment described in your application is conditionally acceptable provided Wellmark submits to the Agency, within twelve (12) months from the date of this letter (December 1, 2012), data demonstrating the efficacy of this product at the rate(s) prescribed on the product label for ULV applications.
- The December 16, 2010, amendment seeks to add a supplemental label to the master label of the referenced product. Likewise, the Agency has determined that your request is acceptable. The supplemental label expires "December 1, 2012".

If Wellmark will need to distribute supplemental labels for this product subsequent to the October 06, 2012 expiration date, then Well mark will need to submit a request to the agency to amend the supplemental label's expiration date.

The requested actions are acceptable provided Wellmark:

- Submits to the Agency, within twelve (12) months from the date of this letter (December 1, 2012), data demonstrating the efficacy of this product at the rate(s) prescribed on the product label for ULV applications.
- 2. Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c) (5) when the Agency requires all registrants of similar products to submit such data.
- 3. Submit two (2) copies of your final printed labeling before you release the product for shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags or drum labels.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Should you have any questions, you may contact Ms. Cheryl Greene directly at (703) 308-0352 or via email at greene.cheryl@epa.gov.

For your reference a stamped copy of the label is included with this letter.

Sincerely,

Linda A. Hollis, Chief

Biochemical Pesticides Branch

Biopesticides and Pollution

Prevention Division (7511P)



WASHINGTON, D.C. 20460

#### DEC 01 2011

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Steven R. Spaulding Senior Director, Regulatory Affairs Wellmark International/Farnam Companies, Inc. 1100 East Woodfield Road, Suite 500 Schaumburg, IL 60173

Subject:

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CURR	ENCES		
	7511P		
	Greene 4		
	November 30, 2011		

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Biopesticides and Pollution

Prevention Division (7511P)

CES				
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Greene				
November 30, 2011				



WASHINGTON, D.C 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

DEC 01 2011

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Biopesticides and Pollution

Prevention Division (7511P)

ENCES		
7511P		
Greene		
November 30, 2011		



#### RE: Fast Track Amendments Nancy Huebl to: Cheryl Greene

12/02/2011 07:13 PM

1 attachment

POF

epa approved ulv 10611.pdf

Hi Cheryl, we may have received this from Leonard Cole. great weekend.

Here is copy. Have a

Nancy

----Original Message----

From: Greene.Cheryl@epamail.epa.gov [mailto:Greene.Cheryl@epamail.epa.gov]

Sent: Friday, December 02, 2011 5:39 PM

To: Nancy Huebl

Subject: RE: Fast Track Amendments

Hi Nancy:

My records do not show that I sent you a stamped label and acceptance letter on October 6, 2011 for 2724-446. Would you please send me -- as soon as you possibly can - a copy of the label and letter that I forwarded to you? I am especially anxious to see the letter and label because it may be that someone else in the division may have sent the letter and label to you and inadvertently neglected to note that the action is closed. .Before I send you the letter and label I alerted you to on November 30, I want to make sure that it will not be a Sorry if this is confusing. Thanks. duplicate.

Cheryl F. Greene

Office of Prevention, Pesticides and Toxic Substances

Office of Pesticide Programs, BPPD/BPB (7511P)

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, N.W.

Washington, DC

Tel: 703 308-0352 Fax 703 308-7026

Email: greene.cheryl@epa.gov

Nancy Huebl <NHuebl@central.com> From: To: Cheryl Greene/DC/USEPA/US@EPA

Leonard Cole/DC/USEPA/US@EPA, Linda Hollis/DC/USEPA/US@EPA Cc:

11/30/2011 03:37 PM Date:

RE: Fast Track Amendments Subject:

Cheryl, I already received a stamped label for 2724-446 dated October 6, 2011. I am however, still awaiting a label for 2724-788. Hope you are doing well. Nancy Huebl

----Original Message----

From: Greene.Cheryl@epamail.epa.gov [mailto:Greene.Cheryl@epamail.epa.gov]

Sent: Wednesday, November 30, 2011 2:14 PM

To: Nancy Huebl

Cc: Cole.Leonard@epamail.epa.gov; Hollis.Linda@epamail.epa.gov

Subject: RE: Fast Track Amendments

#### Hi Nancy:

I have completed the 2724-446 application. Its on Linda's desk for signature. I should get it back tomorrow and will forward an electronic copy of the label and acceptance letter to you as soon as get it. I'm working to complete 2724-788 (RF2047 DP) now. I expect to get it to Linda by cob tomorrow. I will keep you posted.

Cheryl F. Greene
Office of Prevention, Pesticides and Toxic Substances
Office of Pesticide Programs, BPPD/BPB (7511P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20004

Tel: 703 308-0352 Fax 703 308-7026

Email: greene.cheryl@epa.gov

From: Nancy Huebl <NHuebl@central.com>
To: Leonard Cole/DC/USEPA/US@EPA

Cc: Cheryl Greene/DC/USEPA/US@EPA, Steve Spaulding

<SSpaulding@central.com>, Mark Taylor <MTaylor@central.com>

Date: 11/15/2011 02:26 PM

Subject: RE: Fast Track Amendments

Leonard, please see below. We still have not received anything back on the 2724-788 RF2047 DP (dust) amendment that is pending since Dec 2010. Please advise status. Thanks.

2724-788: RF2047 DP (dust formulation) label amendment. We have not received anything on this action yet. We are looking for a stamped label. There was a Linda Hollis email response to Steve that an interim efficacy study we submitted was reviewed and is questionable and that a letter would be forwarded to us on that, not yet received.

Nancy Huebl 847-330-5376

----Original Message----

From: Cole.Leonard@epamail.epa.gov [mailto:Cole.Leonard@epamail.epa.gov]

Sent: Thursday, October 13, 2011 2:09 PM

To: Nancy Huebl

Cc: Steve Spaulding; Greene.Cheryl@epamail.epa.gov

Subject: RE: Fast Track Amendments

Hi Nancy,

I will have all of the corrected information to you by COB tomorrow. I simply need to confirm one item with our efficacy reviewer. Thanks for your patience.

Leonard S. Cole, Jr., Senior Regulatory Specialist Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division (7511P)
U.S. Environmental Protection Agency Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
Phone: 703.305.5412
Email: cole.leonard@epa.gov

From: Nancy Huebl <NHuebl@central.com>
To: Leonard Cole/DC/USEPA/US@EPA

Cc: Steve Spaulding <SSpaulding@central.com>

Date: 10/11/2011 04:42 PM

Subject: RE: Fast Track Amendments

Leonard, thanks so much for your call on our pending actions. Sorry for the confusion and here is what is outstanding:

2724-427 RF9811 EC (was Zoecon RF342 EC) - liquid formulation We received an EPA stamped approved label dated August 10, 2011. The stamped label did not include a cover letter. When I spoke to Cheryl Greene in August she advised me that the letter would state the parameters/timelines for the data we agreed to submit. That is the letter that we are requesting.

2724-788-RF2047 DP (dust formulation) label amendment. We have not received anything on this action yet. We are looking for a stamped label. There was a Linda Hollis email response to Steve that an interim efficacy study we submitted was reviewed and is questionable and that a letter would be forwarded to us on that, not yet received.

Hopefully, this is clearer, if you have any questions, give me a call and we'll try again. Thanks very much for your help on resolving these outstanding actions.

Nancy Huebl
847-330-5376

----Original Message-----

From: Cole.Leonard@epamail.epa.gov [mailto:Cole.Leonard@epamail.epa.gov]

Sent: Tuesday, October 11, 2011 3:02 PM

To: Nancy Huebl

Subject: Fw: Fast Track Amendments

As promised, please see attached.

Leonard S. Cole, Jr., Senior Regulatory Specialist

Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
Phone: 703.305.5412
Email: cole.leonard@epa.gov

---- Forwarded by Leonard Cole/DC/USEPA/US on 10/11/2011 04:01 PM -----

From: Linda Hollis/DC/USEPA/US

To: Steve Spaulding <SSpaulding@central.com>

Cc: Cheryl Greene/DC/USEPA/US@EPA, Leonard Cole/DC/USEPA/US@EPA

Date: 10/06/2011 04:17 PM

Subject: Re: Fast Track Amendments

See response in red below.

Linda A. Hollis, MS
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)
Visit http://www.epa.gov/pesticides

"The journey of 1000 miles begins with one step.....Take the step"

From: Steve Spaulding <SSpaulding@central.com>

To: Linda Hollis/DC/USEPA/US@EPA

Date: 10/05/2011 03:49 PM

Subject: Fast Track Amendments

Hi Linda -

We do not seem to be making progress on the Wellmark fast track amendments since the BPPD/BPIA meeting in July. The following is the status of 4 outstanding fast track amendments:

1. Zoecon RF-342EC - EPA Reg. No. 2724-788. Completed.

Email from L. Cole with letter and label coming today.

Submitted November 23, 2010.

Resolved conditions for approval with BPPD August

5, 2011

Received by email stamped approved label August 10,

2011

 Still have not received the approval letter despite asking for it several times. We did not want to submit state registrations without making sure there were no changes to the label (verbally communicated from Cheryl Greene), therefore we missed the entire stored product pest season.

2. RF2047 DP - EPA Reg. No. 2724-788 Completed. Email from

L. Cole with letter and label coming today.

- Submitted November 23, 2010 at the same time as #1 since the amendment was basically the same for this product which is a dry version of #1. Interim efficacy study submitted has been reviewed and is questionable. Letter to be forwarded tomorrow.
- . Review has not been initiated. We missed the entire stored product pest season.
- 3. Altosid Liquid Larvacide (SR 20) EPA Reg. No. 2724-446. Add ULV application.Completed. Email from L. Cole with letter and label coming today.

Submitted 12/14/2010

- Review not initiated. Missed entire mosquito season.
- 4. Altosid Liquid Larvacide (SR5) EPA Reg. No. 2724-392 Add ULV applicationCompleted. Email from L. Cole with letter and label coming today.

Submitted 12/14/2010 at the same time as #3 and the amendment is the same as #3.

. Review has not been initiated. We missed the entire mosquito season.

Taken alone, these amendments may not seem to mean much; however, taken together failure to get these amendments approved in a reasonable timely manner resulted in lost revenue for Wellmark this year. That is not what business needs in this economy.

One of the reasons I am pointing this situation out again, is that I am preparing another fast track alternate formulation amendment. This is a simple substitution of of the preservative with

in Altosid Liquid Feed Supplement (EPA Reg. No. 2724-505). This is a time sensitive submission since we have to start manufacturing for the cattle horn fly season early next year. I understand that fast track amendments are lower than PRIA actions in priority and that resources are at a premium but it seems to me there has to be a way to improve processing fast track amendments. As you know, Maintenance Fees are supposed to cover these amendments. If there is any way that we can help alleviate this problem through Wellmark or BPIA, please let me know. In the meantime, I will make this fast track submission and hope that it can be reviewed in a timely manner. In addition, I hope that you are able to free up resources to complete the review of the fast track amendments that have been pending for almost a year. We will be discussing progress on Fast Track Amendments at the BPPD/BPIA meeting that is being scheduled for mid-October.

Please let me know if you have any questions or comments. Steve

\*\*\*\*\*\*\*\*\*\*

Steven R. Spaulding Senior Director, Regulatory Affairs Wellmark International / Farnam Companies, Inc. dba Central Life Sciences (847) 330.5380 ph (847) 330.5391 fx sspaulding@central.com Disclaimer: This communication and any attachments contain private, confidential, privileged and/or proprietary information intended solely for the Recipient(s) named above. If you are not the intended Recipient, any use, dissemination, distribution or copying of the communication is strictly prohibited. If received in error, we apologize and ask that you please notify the Sender by returning this e-mail and permanently deleting this communication from your computer, including destruction of any printed copies. Any views expressed herein are not necessarily those of the Company represented by this e-mail source. No contracts, agreements or legally binding understandings may be entered into solely by an e-mail communication

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RE: Fast Track Amendments Cheryl Greene to: Nancy Huebl Cc: Cole.Leonard, Linda Hollis

11/30/2011 03:13 PM

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U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20004

Tel: 703 308-0352 Fax 703 308-7026

Email: greene.cheryl@epa.gov

Nancy Huebl

Leonard, please see below. We still have not re...

11/15/2011 02:26:51 PM

From:

Nancy Huebl <NHuebl@central.com>

To:

Leonard Cole/DC/USEPA/US@EPA

Cc:

Cheryl Greene/DC/USEPA/US@EPA, Steve Spaulding <SSpaulding@central.com>, Mark Taylor

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Date: Subject:

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Cc: Steve Spaulding; Greene.Cheryl@epamail.epa.gov

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Leonard S. Cole, Jr., Senior Regulatory Specialist Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division (7511P)
U.S. Environmental Protection Agency Ariel Rios Building
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Phone: 703.305.5412
Email: cole.leonard@epa.gov

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Nancy Huebl
847-330-5376

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To: Nancy Huebl

Subject: Fw: Fast Track Amendments

As promised, please see attached.

Leonard S. Cole, Jr., Senior Regulatory Specialist Biochemical Pesticides Branch Biopesticides and Pollution

RO	UTING & TRANSMI	ITTAL SLIP	November 30, 2011		
то	1:		Initials	Date	
1	Linda Hollis		LH	11.20.1	
2.	Cheryl Greene				
	Action	File		Note And Return	
X	Approval	For Clearance		Per Conversation	
	As Requested	For Correction		Prepare Reply	
	Circulate	For Your Information		See Me	
	Comment	Investigate		Signature	
	Coordination	Justify	x	Initials, Concurrence	

SUBJECT:

Label Amendments for Altosid Liquid Larvicide

EPA Reg. No. 2724-446

Submissions dated: December 14, 2010 adding ULV instructions, revising ingredient and precautionary statements (EPA Decision #443311) and December 16, 2010 – Adding Supplemental labeling (EPA Decision # 444119) and December 30, 1994 (EPA Decision 121710) revising CSF to identify an active ingredient.

REMARKS – Attached is a conditional (accepted with comments) revised acceptance letter for the above referenced actions. This letter accepts: ULVapplications for the product; supplemental labeling for the product and various updates to the label including precautionary statement, directions for use, address, etc.. Additional this letter closes out an open CSF (inert ingredient) action from December 30, 1994. (The latter action is not referenced in the attached letter.). Please review the letter and if all is well sign and concur. Let me know if you have questions.

FROM: Cheryl Greene	Room NoBldg. 8956
	Phone No
	703 308-0352



#### ACCEPTANCE LETTER AND STAMPED LABEL FOR EPA REG # 2724-427

Cheryl Greene to: Nancy Huebl Cc: Linda Hollis, Cole.Leonard 10/06/2011 05:26 PM

#### Hi Nancy:

Attached please find a copy of the signed acceptance letter and copy of stamped accepted label for your label amendment date November 23, 2011 (Reg. # 2724-427). Letters and stamped labels for RF2047 DP – EPA Reg. No. 2724-788, Altosid Liquid Larvacide (SR 20), EPA Reg. No. 2724-446, Altosid Liquid Larvacide (SR5) – EPA Reg. No. 2724-392 will follow. Let me know if you have questions.

1 attachment	
ADE	
[Untitled].pdf	- [Untitled].pdf

Cheryl F. Greene
Office of Prevention, Pesticides and Toxic Substances
Office of Pesticide Programs, BPPD/BPB (7511P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20004

Tel: 703 308-0352 Fax 703 308-7026

Email: greene.cheryl@epa.gov

Label Review Sheet

FILENAME:

g:\regulatory\LABELS\027244 46\epa amend container ulv

COVERSHEET UPDATE: December 2010

app 1210

12/14/10

PRODUCT:

APPROVED:

ZOECON RF-437 MOSQUITO GROWTH

EPA REG. NO.:

2724-446

**REGULATOR SR-20** Amendment submitted

SUPERCEDES:

7/9/09

OVERVIEW: : <u>Label amendment to incorporate approved 24C language for control of mosquito larvae using ULV applications</u>

	Description of Major Changes
1	Added claim to reflect addition of 24c ULV application for mosquito larvae Ingredient Statement: deleted zeros in percentages, not needed
2	Precautionary Statements: updated per current Label Review Manual
<u>3-5</u>	Directions for Use. Updated some sentences to active tense  Added directions for control of mosquito larvae using ULV application per the approved 24C language
6 & 7	Added street address

1

[] optional wording

#### **ZOECON RF-437 MOSQUITO GROWTH REGULATOR SR-20**

Alternate brand names:

Zoëcon® Altosid® Liquid Larvicide Concentrate

Strike Professional Midge Control

Prevents emergence of adult floodwater mosquitoes

[Prevents the emergence of adult filter [moth] flies, and midges]

[Keeps infestations under control]

Prevents emergence of adult fleas up to 8 weeks outdoors

Controls pre-adult fleas (larvae) up to 8 weeks Biorational [approach to] flea control outdoors

Microencapsulated Formula

Prevents adult mosquito emergence (including those which may transmit West Nile Virus)

For control of mosquito larvae using ULV application

ACTIVE INGREDIENT:

(S)-Methoprene (CAS #65733-16-6)	1%	 Deleted: .0
OTHER INGREDIENTS:	Toronto .	 Deleted: 0
TOTAL 100	1%	 Deleted: .0

Formulation contains 1.72 lb/gal (205.2 g/l) active ingredient

### KEEP OUT OF REACH OF CHILDREN CAUTION

See Back Panel For Additional Precautionary Statements

BECAUSE OF THE UNIQUE MODE OF ACTION OF ZOECON RF-437 MOSQUITO GROWTH REGULATOR SR-20, SUCCESSFUL USE REQUIRES FAMILIARITY WITH SPECIAL TECHNIQUES FOR APPLICATION TIMING AND TREATMENT EVALUATION. SEE GUIDE TO PRODUCT APPLICATION OR CONSULT LOCAL MOSQUITO ABATEMENT AGENCY.

EPA Reg. No. 2724-446 EPA Est. No.

NET CONTENTS:

1

#### PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing qum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

Call a poison co	ontrol center or doctor immediately for treatment advice.
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
If on skin or clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> </ul>
Have the produ	ct container or label with you when calling a poison control center or doctor, or ient. You may also contact 1-800-[phone number] for emergency medical

[Note: First Aid statement paragraph format may be used if space is limited.]

#### **ENVIRONMENTAL HAZARDS**

Do not contaminate water when disposing of rinsate or equipment washwaters.

**IINTRODUCTION** 

[Zoecon RF-437 is a unique product that controls [mosquitoes][filter [moth] flies (*Psychoda* spp.)][midges (*Chironomidae*)] and other nuisance aquatic insect species [infesting waste water treatment facilities]. Zoecon RF-437 contains an insect growth regulator (IGR) that is effective on the developing [immature] stages of insect pests. Zoecon RF-437 does not kill adults but affects the larval stages as they grow and develop. Zoecon RF-437 stops the formation of pupa of insect pests, thereby eliminating adult populations. Zoecon RF-437 stops the cycle of reproduction, keeping pest infestations under control. Continued use of the product prevents these pests from rebounding into unmanageable infestations.]

#### DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

#### MIXING AND HANDLING INSTRUCTIONS:

- SHAKE WELL BEFORE USING. Zoecon RF-437 may separate on standing and must be thoroughly agitated prior to dilution.
- 2. Do not mix with oil; use clean equipment.
- Partially fill spray tank [container] with water; then add the labeled amount of Zoecon RF-437, agitate and complete filling. Mild agitation during application is desirable. [Accomplish agitation by use of recirculation pump, mixer, air pump, or other suitable equipment.]
- Use spray solution within 48 hours; always agitate before spraying.

#### **APPLICATIONS**

**Mosquito Control:** Zoecon RF-437 must be applied to 2nd, 3rd, or 4th larval instars of floodwater mosquitoes to prevent adult emergence. Treated larvae continue normal development to the pupal stage where they die. This insect growth regulator has no effect when applied to pupae or adult mosquitoes. Zoecon RF-437 has sufficient field life to be effective at label rates when applied to larval stages under varying field conditions. For further information, see **Guide to Product Application**.

#### For Control of Mosquito Larvae Using ULV Application:

For ground application to terrestrial sites, apply at the rate of % - 1 ounce of product per acre to water-holding containers and other small bodies of water that breed mosquitoes. Use equipment capable of applying a fine mist or ULV. Follow equipment manufacturer's recommendations when making applications. Direct spray applications to sites where mosquitoes breed. These sites include tires and tire piles, potted plants, tree holes, garbage bins, cans, birdbaths, rain barrels, and other water-holding containers and small bodies of water.

[Waste Water Treatment Facility Pests: Use Zoecon RF-437 in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where midges, filter [moth] flies, and other nuisance aquatic insect pests are a problem.]

#### [What to Expect in Waste Water Treatment Facilities] [Continuous Flow Sewage {waste water}

In order to achieve effective results, Zoecon RF-437 must be applied on a daily basis for at least 2 weeks. Failure to apply the material on a daily basis during the treatment phase may result in erratic results. Following initial applications of Zoecon RF-437, a gradual reduction in the number of adult pests will be seen over approximately a 1 week period. Reduction in adult populations will be very noticeable within a two week period following continuous application. Due to varying conditions or heavy infestations, the period to expect control may be longer. Since the mode of action of Zoecon RF-437 is to prevent adult emergence, existing adults and pupa present at the time of initial application will complete their life cycle.

As adult suppression peaks, use a maintenance rate of Zoecon RF-437 for continuous protection from population rebound. However, if application of Zoecon RF-437 is halted following population suppression, rebound of the population can be expected within 2 to 3 weeks after stopping application. For continuous suppression throughout the pest season, continue application of Zoecon RF-437.

#### Sludge or Solid Waste Applications

For solid waste applications, use 5 ounces per million gallons of sludge or solids. Apply the dilution until the drying beds have been filled. Following filling of the drying beds, the application of the dilution may be halted. Make applications of the dilution at the influent side as the sludge or solids enter into the drying beds. Application of Zoecon RF-437 to solids will prevent the emergence of adult insect pests thereby keeping infestations under control.]

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#### METHODS OF APPLICATION

**Aerial:** Use the amount of Zoecon RF-437 listed below in sufficient water to give complete coverage. One-half to 5 gallons of spray solution per acre (4.7 to 46.8 liters/hectare) is usually satisfactory. Do not apply when weather conditions favor drift from areas treated.

**Ground:** Determine the average spray volume used per acre by individual operators and/or specific equipment. Mix Zoecon RF-437 in the appropriate volume of water to give the rate per acre shown below.

[Waste Water Treatment Facilities:] [Dilute Zoecon RF-437 with water prior to use. Apply Zoecon RF-437 with a metering pump, drip bucket or other suitable equipment. Metering pumps are the most efficient and accurate method of application. Appropriate dilution of product will be influenced by the method of application. Depending on the dosage rate, prepare the desired volume of dilution to apply over a {6 – 8 hour period} {24 hour period (day tank)}, or in cases of sludge beds, applied until the beds have been filled. When using delivery devices, it is important to calibrate the device to deliver the required amount of Zoecon RF-437 over a {6 – 8 hour period} {24 hour period}. {Sufficient material may be mixed in advance to provide for applications longer than 24 hours.}][For best results, use metering pumps that are capable of deliverying material for greater than 24 hours.]

Deleted: Make

Deleted: application of

Deleted: by use of

#### APPLICATION RATE

**Mosquitoes:** Apply  $^3/_4$  to 1 fl oz of Zoecon RF-437 per acre (55 to 73 ml/hectare) in water as directed.

#### For Control of Mosquito Larvae Using ULV Application:

Apply at 3/4 - 1 ounce per acre. Reapply as breeding sites become reinfested or when monitoring indicates an increase in adult populations.

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#### [Waste Water Treatment Pests:]

[Initial Application - 4 - 5 ounces Zoecon RF-437 per 1 million gallons of sewage [waste water] in sufficient water to uniformly apply at the influent side over a 24 hour period.]

[Maintenance Rate - 2.5 - 3.0 ounces Zoecon RF-437 per 1 million gallons of sewage [waste water] in sufficient water to uniformly apply at the influent side over a 24 hour period.]

[To achieve effective results, make initial application rates on a daily basis for 2 weeks without interruption. Use sufficient water/Zoecon RF-437 to achieve uniform application to sewage [waste water] over a 24 hour period. Apply the dilution at the influent side of the particular area to be treated.]

Deleted: Make application of

[Maintain initial rate of application for two weeks and then follow the directions for the maintenance rate for continued effectiveness.]

4

[Application to Waste Water - Trickling Filter:

Apply 5 ounces Zoecon RF-437 per 1 million gallons of sewage [waste water] in sufficient water to uniformly apply the material. Apply at times of low periods of flow (typically evening through early \_\_\_\_\_ Peleted: Make applications morning hours) for 6 - 8 hours. Discontinue treatment during peak flow periods and repeat applications the following day during the low flow period. Continue this application method for 7 to 10 days or until suppression of pests is achieved. Repeat applications every 15 days or as necessary to control pests.1

Fleas: Apply 1 fluid ounce of Zoecon RF-437 per 1000 square feet in water as directed.

#### APPLICATION SITES

Pastures: Zoecon RF-437 may be applied after each flooding without removal of grazing livestock.

Rice: Zoecon RF-437 must be applied to 2nd, 3rd, and/or 4th instar larvae of mosquitoes found in rice, usually within 4 days after flooding. Zoecon RF-437 treatment may be repeated with each flooding.

Intermittently Flooded Noncrop Areas: Apply Zoecon RF-437 as directed above when flooding may result in floodwater mosquito hatch. Typical sites include freshwater swamps and marshes, salt marshes, woodland pools and meadows, dredging spoil sites, drainage areas, waste treatment and settling ponds, ditches and other natural and manmade depressions.

Crop Areas: Apply Zoecon RF-437 to irrigated croplands after flooding to control mosquito emergence. Examples of such sites are vineyards, rice fields (including wild rice), date palm orchards, fruit and nut orchards and berry fields and bogs. Irrigated pastures may be treated after each flooding without removal of livestock.

Dense vegetation or canopy areas: Apply a Zoecon RF-437 sand mixture using standard granular dispersal equipment. For detailed preparation instructions, refer to Guide to Product Application.

For Fleas Outdoors: (1) When using a hose-end sprayer, place 0.75 ounces of Zoecon RF-437 in bottle, add 6 ounces of water and apply at low pressure. (2) Make sure to apply at 0.75 ounces of Zoecon RF-437 per 15 gallons of water. (3) Apply 0.75 ounces of Zoecon RF-437 in 15 gallons of water to every 750 square feet of residential turf. (4) Pay particular attention to areas where pets frequent, such as, in and around dog houses and runs, and around shrubs, outside decks. and porches. (5) If a large population of fleas is present, use [an outdoor flea control product][brand name of outdoor flea control product] for initial kill of adult fleas.

[Waste Water Treatment Facilities: Apply Zoecon RF-437 to sewage as it flows into trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures. stagnant or standing water, or other areas of waste water facilities where pests are a problem.

Deleted: Make applications of

Apply Zoecon RF-437 as the sewage enters (influent areas) the targeted processing area. Failure | Deleted: Make applications of to add the material at the influent side may result in erratic results.]

5

**TANK MIXING INSTRUCTIONS:** Zoecon RF-437 may be tank mixed with liquid *Bacillus thuringiensis* variety *israeliensis* (*B.t.i.*) formulations. The ratio of *B.t.i.* to Zoecon RF-437 is to range from 24:1 to 50:1 (volume/volume). For example, to prepare a 50:1 tank mix, add 1 gallon of RF-437 to 50 gallons of *B.t.i.* This tank mix can be applied to sites listed above at rates of 2 to 16 fluid ounces/acre (0.15-1.2 liters/hectare).

The user, at his discretion can [tank] mix Zoecon RF-437 with an adulticide currently registered for use unless the product label prohibits such mixing. Use of the resulting tank mixture must be used in accordance with the more restrictive label limitations and precautions.

**CHEMIGATION:** Refer to supplemental labeling entitled "Guide to Product Application" for use directions for chemigation. Do not apply this product through any imigation system unless the supplemental labeling on chemigation is followed.

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Storage: Store in a cool place, away from other pesticides, food and feed. In case of leakage or spill, soak up with sand or another absorbent material. Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal: Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptyng. Triple rinse as follows. Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

For information, call 1/800-XXX-XXXX or visit our Web site: [URL].

Wellmark International 1501 East Woodfield Road 200W Schaumburg, IL 60173

Made in USA

## ZOECON RF-437 MOSQUITO GROWTH REGULATOR SR-20 PREVENTS EMERGENCE OF ADULT FLOODWATER MOSQUITOES

#### GUIDE TO PRODUCT APPLICATION

#### FOR THE FIRST TIME USER

ZOECON RF-437 MOSQUITO GROWTH REGULATOR SR-20 (SR-20) is the result of extensive research into the intricacies of natural biochemical and physiological development of insects. New chemical technology and biological findings were combined to develop a unique mosquito larvicide.

SR-20, an insect growth regulator (IGR), acts by inducing morphological changes which interfere with normal development. These effects, not immediately apparent, result in the failure of adult mosquitoes to emerge from pupae. SR-20 is <u>not</u> a conventional pesticide. It does not produce the nondiscriminatory rapid, directly toxic effects that are associated with traditional larvicides. SR-20 differs from other larvicides you may have used only in the manner and time course of its action after application.

SR-20 is applied to second, third or fourth instar larvae using standard larviciding equipment in a manner similar to other larvicides. After application to second, third or fourth instar larvae at recommended rates, absolutely no effects on larvae will be observed. They will continue developing normally and will pupate. Pupae will appear unaffected, but will eventually die. Adults will not emerge. Infrequently, a few adults may be seen at the water surface but they will have abnormalities preventing flight and will not survive. Because the effect of SR-20 is neither larval death nor widespread mortality immediately following pupation, the number of adults which emerge is the only criterion for accurately assessing control. Checks by dip counts during larval and pupal stages will give no measure of effectiveness.

Refer to the following diagram and checklist, in addition to label instructions for guidance in timing of application and performance evaluation. They will assist you in obtaining the best possible results with this unique product.

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For information, call 1/800-XXX-XXXX

The information presented herein, while not guaranteed, is to the best of our knowledge true and accurate. No warranty or guarantee, express or implied, is made regarding the performance or stability of any product, since the manner of use and conditions of storage and handling are beyond our control.

CHECK LIST
Things to remember when using SR-20

#### DO the following:

- 1. DO treat second, third and/or fourth instar larvae, not pupae or adults. (First instar larvae are so small they are not readily detectable.)
- 2. DO wait until treated larvae have pupated. Then collect pupae and transfer to laboratory to observe for emergence of adults.
- 3. DO observe pupae for several days, since death of IGR treated mosquitoes occurs when pupae would normally emerge as adults. (Careful observation is necessary since dead pupae decompose rapidly and thus are not easily seen.)
- 4. DO monitor emerging adults at the treatment site. This absolutely requires that emergence traps be placed in treatment areas to capture adult mosquitoes as they emerge.

#### DO NOT do the following:

- 1. DO NOT take dip counts of larvae after treatment for the purpose of performance evaluation. Normal looking larvae will be present.
- DO NOT take dip counts of pupae after treatment for the purpose of performance evaluation. Normal looking pupae will be seen but these will not develop into normal adults.
- DO NOT think SR-20 has failed if some adult mosquitoes are flying in treated areas; they probably have flown in from nearby untreated areas. Numbers 2 and 4 of the "DO" checklist are the only methods of accurately assessing effectiveness.
- DO NOT spray again, either with SR-20 or a conventional insecticide, because larvae or pupae are present after application. This is normal. The effectiveness of SR-20 can only be measured by lack of adult emergence.

LIFE CYCLE OF MOSQUITO WHEN TO APPLY ZOECON SR-20 MOSQUITO GROWTH REGULATOR

#### Preparation of ALTOSAND® Granular Formulation

An "On-Site" Method of Preparing a Granular Formulation of SR-20

#### INTRODUCTION

A method of application of SR-20, using sand as a carrier, has been developed for use in floodwater mosquito breeding areas with dense vegetation or canopy. The characteristics of ALTOSAND provide excellent foliage penetration, insuring that the active ingredient reaches the water where it is released from the sand.

ALTOSAND will prevent the emergence of species of the floodwater mosquito complex when applied to second, third or fourth larval instars at a rate of ten to thirteen pounds per acre.

#### PREPARATION INSTRUCTIONS

The following materials are required to prepare a 100 lb. batch of ALTOSAND:

99 lb washed, dry sand (20-45 mesh) 0.5 lb SR-20 (15 fluid oz/lb) 0.5 lb HiSil 233 (silicon dioxide) Small Funnel Cement Mixer

- 1. Measure the time required for a level funnel full of sand to empty.
- Into a rotating-type mixer, place 99 lb of dry (20-45 mesh) sand. While the mixer is rotating, slowly pour 0.5 lb (7.5 fl oz) of SR-20 onto the sand. (If better wetting is required, SR-20 may be diluted in up to an equal volume of water.)
- 3. Mix until the sand is uniformly coated with SR-20 (usually 5 to 10 minutes).
- 4. Stop the mixer and add 0.5 lb of HiSil 233. Cover the mixer to reduce dust. Start the mixer and run for approximately 5 minutes. (The quantity of HiSil 233 necessary to achieve a dry, free-flowing mixture will vary depending on the particle size distribution and moisture of the sand.)
- 5. Compare the flow rate of the ALTOSAND mixture with that of untreated sand in Step No. 1. Add more HiSil if it flows significantly slower and reduce the amount of HiSil in subsequent batches if the mixture flows at the same or a faster rate and is excessively dusty.

Apply at a rate of 10 to 13 lb of the final mixture per acre, using standard granular dispersal

#### APPLICATION RATE AND METHODS

equipment.							
				7			

Chemigation: Apply this product only through flood (basin), furrow or border irrigation systems. Do not apply this product through any other type of irrigation system. Crop injury, lack of effectiveness or illegal pesticide residues in the crop can result from nonuniform distribution of treated water. If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

**Flood (Basin), Furrow and Border Chemigation:** Systems using a gravity flow pesticide dispensing system must meter the pesticide into the water at the head of the field and downstream of a hydraulic discontinuity such as a drop stucture or weir box to decrease potential for water source contamination from backflow if water flow stops.

Systems utilizing a pressurized water and pesticide injection system must meet the following requiremments:

- \* The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
- The pesticide injection pipeline must contain a functional, automatic quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- \* The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- \* The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where the pesticide distribution is adversely affected.
- Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

A pesticide supply tank is recommended for the application of SR-20 by chemigation.

ALTOSAND is a registered trademark of Wellmark International.

EPA Reg. No.: 2724-446

## MATERIAL TO BE ADDED TO JACKET

REG #: 2724-446	
Description: Zoecon RF-437 Mosquito Gra Regulator SR-20	uth
if applicable, check all that are attached:	
new stamped accepted label	Se
new CSF (Basic And New Alternate Some	400
notification	S
other:	C
Instructions:  Attach this sheet to the top of ALL material sent to the file room (both and new material in jackets). This sheet will be imaged; a clear description of the material in the e-jacket. Remove staples from all material returning loose paper then hold together with a binder or paper clip. be placed in the CSF folder (if returning jacket) or covered with a red returning loose paper). Material to be returned to file room should be appropriate bin.	ription will aid rial. If CSFs should <u>CBI sheet</u> (if
Reviewer: Menyon Adams Date: 17 Ma	410
Phone: (703) 347-8496 Division: BPPD	-

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Regulatory Type: Product Registration - Section 3 Fee For Service	Act Charles	To the same of the	Enter M	fore Information
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Company: 2724 WELLMARK INTERNATIONAL	V		(a) Van	
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91		-		
Product #: 2724-446 Product Name: ZOEGON RF-437 MOSQUITO	GROVVTH REG	Ū	- 10	
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Occist 431432.

Due date: 6/24/10

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

March 30, 2010

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JAMES MCFADDEN, PH.D. WELLMARK INTERNATIONAL 1501 E. WOODFIELD ROAD, SUITE 200 WEST SCHAUMBURG, IL 60173

PRODUCT NAME: ZOECON RF-437 MOSQUITO GROWTH REGULATOR SR-20

COMPANY NAME: WELLMARK INTERNATIONAL

OPP IDENTIFICATION NUMBER: EPA FILE SYMBOL: 2724-446 EPA RECEIPT DATE: 03/26/10

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 91, at (703) 308-8733.

Sincerely.

P. K. TROOKE

Front End Processing Staff Information Services Branch Information Technology & Resources Management Division \*Pages 107-108 Claimed confidential by submitter\*

<b>⇔</b> EPA	United State  Environmental Protect Washington, DC	ection Agency 2 20460	Kcylstration  X Amendment Other	2070-0060. Approval expires 2-28-98 OPP Identifier Number
	App	olication for Pesticide - Sec	ection I	
Company/Product Number     Wellmark International/27;		2. EPA Product Mana Linda Hollis		3. Proposed Classification
Regulator SR-20	Zoecon RF-437 Mosquito Growth	PM# BPPD Branch Chief	rf	X None Restricted
Wellmark International 1100 East Woodfield Ros Schaumburg, Illinois 601		6. Expedited Revio (b)(i), my product is EPA Reg. No. Product Name	iew. In accordance with FIFRA s similar or identical in composition	. ,, ,
		Section - II		The state of the s
	se to Agency letter dated	Age *Me Oth	oal printed labels in response to ency letter dated e Too" Application ner - Explain below o add alternate approved source o	of the active ingredient.
		Section - III		
1. Material This Product Will	l be Packaged In:			
Child-Resistant Packaging	Unit Packaging	Waler Soluble Packagin	2. Type of Container	
Yes No	Yes  X No  If "Yes Unit No. per	Yes No	Metal X Plastic Glass Paper	
* Certification must be submitted	Packaging wgt. container		ontainer Other (Spec	aify)
3. Location of Net Contents Inf	, , , ,	Petail Container	5. Location of Label Directions  X On Label	
X Label Co	X Pa		X On Label On Label Accompan	nying Product
		2.31.32.3		
		Section - IV	White and Kana	
Contact Point (Complete Name     Steven R. Spaulding	items directly below for identification	of individual to be contacted, if ne Title Senior Director Regulatory Aff	Telepho	tion.) one No. (Include Area Code) 30-5380
	atements I have made on this form and all any knowingly false or misleading statem			6. Date Application Received (Stamped)
2. Signature	R. Fauldin	3. Title Senior Director Regulatory Affa	fairs	
4. Typed Name Steven R. Spaulding	Ţ	5. Date 25-Mar-10		

## Fee for Service

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This package includes the following	for Division		
<ul><li>New Registration</li><li>Amendment</li></ul>	○ AD ● BPPD ○ RD		
Studies? Fee Waiver? volpay % Reduction:	Risk Mgr. 91		
Receipt No. S	870845		
EPA File Symbol/Reg. No.	2724-446		
Pin-Punch Date:	3/26/2010		
This item is NOT subject	to FFS action.		
Action Code:	Parent/Child Decisions:		
Requested:			
Granted:			
Amount Due: \$			
□ Inert Cleared for Intended Use	Uncleared Inert in Product		
Reviewer: Charas Bruce land	Date: 3 /30 /10		
Remarks:			
CSF Amendment			

Steven R. Spaulding Senior Director Regulatory Affairs Wellmark International 1100 East Woodfield Road, Suite 500 Schaumburg, Illinois 60173

Subject: Zoecon RF-437 Mosquito Growth Regulator SR-20

EPA Registration No. 2724-446

Amendment to basic formulation and to add a proposed new alternate formulation

Decision #: 431432

Application Dated: March 25, 2010

Dear Mr. Spaulding:

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(5), is acceptable provided that you submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c) (5) when the Agency requires all registrants of similar products to submit such data. The Basic and Alternate Confidential Statements of Formula (CSFs) have been added to your file as current and updated. Please note that all other CSFs are considered outdated and obsolete. Should you have any questions, you may contact Ms. Menyon Adams directly at 703.347.8496 or via email at adams.menyon@epa.gov.

Sincerely,

Linda A. Hollis, Chief

Biochemical Pesticides Branch

Biopesticides and Pollution

Prevention Division (7511P)

	CONCURRENCES		
ABOL > 15112			
NAME CANS			
E CS/12/10			

\ Form 1320-1A (1/90)

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# BPPD Formulation Amendment Check List Fast Track ☑ and PRIA Actions B680 ☐, B681 ☐,B730☐

4700	A Reg. No.: 2724446 RAL: Menujus Application Date: 03/29
#	Check list Item
1.	Application Form (EPA Form 8570-1) - signed & complete including package type? IF NO, STOP! Call applicant and have them correct application and resubmit.
2.	Final printed labeling received for previous action? IF NO, STOP! E-mail applicant and request final printed labeling.
3.	Does the registration notice have terms/conditions (ex. storage stability data)?
	If so have the terms/conditions been met?
4.	Confidential Statement of Formula (CSF) EPA Form 8570-4 Basic Formula ☑ Alternate Formula(s) ☑
a.	CSF Review completed? IF YES, SKIP to next item.
Ь.	CSF is signed and dated? IF NO, CALL APPLICANT.
c.	Completely filled out: CAS numbers, pH, flashpoint, flammability, if applicable?
d.	Are the totals accurate?
e.	Certified limits agree with 40 CFR 158.175? Note that if preliminary or 5 batch analysis differ from Section 158.175(b), limits based on batch analysis would need to be proposed under Section 158.175(c).
f.	Viability (if live microbial, i.e., cfu/gram)?  NA
g,	PC codes assigned on CSF for actives & inerts plus 40 CFR 180.910, 180.920, and 180.930 codes noted for products that have food or feed uses?
h.	List 1 inert ingredient(s) present in the formulation?
i.	Alternate formula(s) do not require different labeling from basic CSF or other alternate CSFs.
j.	Source for a.i. is a registered pesticide? (When a proposed alternate or new basic formula involves a new registered manufacturing-use product as the active ingredient source it must be determined whether the manufacturing-use products used to formulate are similar enough to warrant use of existing product specific data such as acute toxicity.)
k.	Does CSF list peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, or wheat commodities? If YES, RAL must evaluate label directions for compliance with 40 CFR 180.1071.
5,	Data and Data Matrix present. (EPA Form 8570-35)
a.	a) Using Selective Method? [[IF NO, SKIP to item 5 and note that data matrix should be used for the cite-all method to indicate the companies to whom offers of compensation were made.]]
b.	Complete Data Matrix. Minimum Data Matrix for registration includes: product specific acute toxicity, product chemistry, and efficacy data for public health pests claimed on label.
c.	Adequate product specific data submitted?

d.	Registered source used for active ingredient? <b>IF YES, SKIP to ITEM 5.</b> (Active ingredient is from a registered source and generic data should be satisfied by registered source. <b>IF NO</b> , generic data needed.
e.	Data passed PR Notice 86-5 for formatting and MRID number assignment?
f,	Public copy of Data Matrix provided? (PRN 98-5)
6.	Certification with Respect to Citation of Data (EPA Form 8570-34): See 40 CFR 152.80-98 and PR Notice 98-5 [Note: If no data are required or submitted, a Certification with Respect to Citation of Data form is not needed. This is often true for minor amendments.]
a.	Did applicant check a Method of Support?
b.	General Offer to Pay checked for Cite-all Method or Cite-all under Selective Method?
c.	Is the form signed and dated?
d.	Check form and Data Matrix; are Exclusive Use data cited from other sources?
	IF YES, is the required authorization letter included in application?  NA □
7.	Formulators Exemption (EPA Form 5870-27)
a.	If registrant is using a registered source active ingredient in the formulation, is form filled out completely and signed?
8.	Science Review completed? Comments:

\*Pages 114-115 Claimed confidential by submitter\*

\*Pages 116-119 Confidential Statement of Formula may be entitled to confidential treatment\*